BIO-RAD

Liquichek™ Urinalysis Control Levels 1 and 2

REF	**435**	Bilevel	12 x 12 mL (6 per level)
	436	Level 1	12 x 12 mL
	437	Level 2	12 x 12 mL
	435X	Bilevel MiniPak	2 x 12 mL (1 per level)

CE IVD EXP **2016-11-30** LOT 65830 Level 1 65831 Level 2 65832

ENGLISH

INTENDED USE

Liquichek Urinalysis Control is intended for use as an assayed quality control urine to monitor the precision of urinalysis test procedures for the analytes listed in this package insert.

SUMMARY AND PRINCIPLE

The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Two levels of control are available to allow performance monitoring within the clinical range.

For customers in Germany: Quality control materials are required for assessment of laboratory performance as described in the "Guideline for Quality Assurance of Medical Laboratory Examinations following the German Medical Association" (Rili-BÄK regulation).

REAGENT

This product is prepared from human urine with added human erythrocytes, simulated leukocytes, constituents of animal origin, chemicals, preservatives and stabilizers. The control is provided in liquid form for convenience.

STORAGE AND STABILITY

This product will be stable until the expiration date when stored unopened at 2 to 8°C. Once the control is opened and stored tightly capped, all analytes will be stable for 30 days at 2 to 25°C. This product should never be frozen.

This product is shipped under refrigerated conditions.

PROCEDURE

This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent being used.

Before sampling, allow the control to reach room temperature (18 to 25°C) and invert the vial several times to ensure homogeneity. After each use, promptly replace the stopper or dispenser tip closure and return to 2 to 25°C storage.

Dispose of any discarded materials in accordance with the requirements of your local waste management authorities. In the event of damage to packaging, contact the local Bio-Rad Laboratories Sales Office or Bio-Rad Laboratories Technical Services.

DISPENSER TIP INSTRUCTIONS

1. Carefully remove the vial screw cap and stopper.
2. Securely attach the dispenser tip to the top of the vial by tightening the original vial screw cap over the dispenser tip.
3. Invert the vial several times to ensure homogeneity.
4. Remove the dispenser tip closure.
5. While holding the urine test strip, gently depress the sides of the dispenser tip. Draw the control sample across all the reagent pads, thoroughly saturating each pad. Do not aspirate control back into the vial.
6. Wipe off dispenser tip and recap with closure being sure not to cross contaminate the level 1 by using level 2 closure.
7. Return vial to 2 to 25°C.
8. A new dispenser tip should be used with each new control vial.

LIMITATIONS

1. This product should not be used past the expiration date.
2. If there is evidence of microbial contamination or excessive turbidity in the product discard the vial.
3. This product is not intended for use as a standard.
4. This product contains gentamicin. Follow the instructions provided by manufacturers of the reagent and/or test system for samples containing gentamicin.

ASSIGNMENT OF VALUES

The results printed in this insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications. Each laboratory should use the results provided only as a reference and establish its own parameters of precision.

Refer to *www.qcnet.com* for insert update information.

SPECIFIC PERFORMANCE CHARACTERISTICS

This product is a stabilized liquid product manufactured under rigid quality control standards. To obtain consistent vial-to-vial assay values, the control requires proper storage and handling as described.

Optional Supplies

RFID Card (enclosed): Refer to Roche Operator's Manual for instructions for use.

Dispenser Tips for Screw Caps (100/package) Item No. 987000 (available separately)

DEUTSCH

VORGESEHENER VERWENDUNGSZWECK

Die Liquichek Urinalysis Control ist eine Qualitätskontolle für in der Urinanalytik angewendete Verfahren zur Bestimmung der in dieser Packungsbeilage angegebenen Analyte, mit Zielwertangaben.

EINLEITUNG UND ZUSAMMENFASSUNG

Die Verwendung entsprechender Kontrollmaterialien dient der objektiven Beurteilung der Qualität von im Labor durchgeführten Untersuchungen und ist ein unerlässlicher Bestandteil der guten Laborpraxis. Die zwei Level dieser Kontrolle ermöglichen eine umfassende Qualitätssicherung über den gesamten klinisch relevanten Bereich.

Für Anwender in Deutschland: Für die Beurteilung der Leistungsfähigkeit sind Qualitätskontrollen gemäß der „Richtlinie der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen" (Rili-BÄK) zu verwenden.

REAGENZ

Dieses Produkt wurde aus Humanurin hergestellt und enthält Zusätze von menschlichen Erythrozyten und simulierten Leukozyten sowie Bestandteile tierischen Ursprungs, Chemikalien, Konservierungsmittel und Stabilisatoren. Die Kontrolle ist gebrauchsfertig, flüssig und dadurch sehr einfach in der Anwendung.

LAGERUNG UND HALTBARKEIT

Dieses Produkt ist bis zum angegebenen Haltbarkeitsdatum stabil, wenn es ungeöffnet bei 2 bis 8°C gelagert wird. Nach dem Öffnen sind alle Analyte 30 Tage stabil, wenn die Kontrolle fest verschlossen bei 2 bis 25°C aufbewahrt wird. Dieses Produkt darf nicht eingefroren werden.

Dieses Produkt wird gekühlt versandt.

HANDHABUNG

Dieses Produkt ist genau wie eine Patientenprobe zu behandeln und in Übereinstimmung mit den Vorschriften des Geräte-, Kit- oder Reagenzherstellers anzuwenden.

Vor Entnahme einer Probe die Kontrolle Raumtemperatur (18 bis 25°C) erreichen lassen und den Inhalt des Fläschchens vorsichtig durchmischen, um die Homogenität sicherzustellen. Nach jedem Gebrauch sofort wieder mit dem Stopfen oder dem Tropfaufsatzverschluss verschließen und bei 2 bis 25°C aufbewahren.

Die Entsorgung aller Abfälle ist nach den geltenden örtlichen Bestimmungen vorzunehmen. Falls die Verpackung beschädigt ist, nehmen Sie bitte Kontakt zur Bio-Rad Niederlassung auf.

ANLEITUNG FÜR DEN GEBRAUCH VON TROPFAUFSÄTZEN

1. Vorsichtig den Schraubverschluss und Stopfen des Fläschchens entfernen.
2. Den Tropfaufsatz auf das Fläschchen setzen und mit dem Originalschraubverschluss des Fläschchens festziehen.
3. Den Inhalt des Fläschchens vorsichtig durchmischen, um die Homogenität sicherzustellen.
4. Den Tropfaufsatzverschluss abnehmen.
5. Den Urin-Teststreifen festhalten und die Seiten des Tropfaufsatzes leicht zusammendrücken. Die Kontrollprobe über alle Reagenzfelder ziehen, um jedes Feld gründlich mit Probenmaterial zu sättigen. Das Kontrollmaterial nicht wieder in das Fläschchen zurücksaugen.
6. Die Spitze des Tropfaufsatzes abwischen und das Fläschchen wieder verschließen. Kreuzkontamination vermeiden: Verschluss von Level 2 nicht für Level 1 benutzen.
7. Fläschchen wieder bei 2–25 °C lagern.
8. Für jedes neue Kontrollfläschchen einen neuen Tropfaufsatz verwenden.

EINSCHRÄNKUNGEN

1. Dieses Produkt nach Ablauf des Haltbarkeitsdatums nicht mehr verwenden.
2. Bei Anzeichen einer mikrobiellen Kontamination oder einer starken Trübung ist die Kontrolle zu verwerfen.
3. Dieses Produkt ist nicht zur Verwendung als Standard geeignet.
4. Dieses Produkt enthält Gentamicin. Bitte die Anweisungen des Reagenz- und/oder Testkitherstellers für Gentamicin enthaltende Proben beachten.

WERTEERMITTLUNG

Die in dieser Packungsbeilage angegebenen Ergebnisse stammen aus Vielfachbestimmungen und gelten speziell für diese Produktcharge. Die Bestimmungen wurden vom Hersteller und/oder von unabhängigen Laboratorien mit vom Hersteller unterstützten Reagenzien durchgeführt; dazu wurde eine repräsentative Stichprobe dieser Produktcharge eingesetzt. Abweichungen im Laufe der Zeit und zwischen verschiedenen Laboratorien sind möglicherweise auf unterschiedliche Labortechniken, Geräte und Reagenzien oder auf Modifikationen der Testmethoden durch den Hersteller zurückzuführen. Jedes Labor sollte die angegebenen Ergebnisse nur als Richtwerte benutzen und seine eigenen Präzisionskriterien ermitteln.

Aktualisierte Zielwerttabellen finden Sie im Internet unter *www.qcnet.com/de*.

SPEZIFISCHE EIGENSCHAFTEN

Dieses Produkt ist ein stabilisiertes, flüssiges Produkt und wurde unter strengen Qualitätsstandards hergestellt. Um reproduzierbare Ergebnisse von Fläschchen zu Fläschchen sicherzustellen, muss die Kontrolle sachgerecht gelagert und wie angegeben gehandhabt werden.

Optionale Artikel

RFID-Karte (beiliegend): Gebrauchsanweisung bitte dem Roche-Bedienungshandbuch entnehmen.

Tropfaufsätze für Schraubverschlussfläschchen (100/Packung), Art.-Nr. 987000 (separat erhältlich)

REF	CE	IVD	EXP	LOT	⚠		EC REP	i	
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BIO-RAD Liquichek™ Urinalysis Control, Levels 1 and 2

FRANÇAIS

UTILISATION
Liquichek Urinalysis Control est une urine titrée de contrôle de la qualité permettant de surveiller la précision des analyses d'urine réalisées en laboratoire pour les analytes dont la liste figure sur cette notice.

INTRODUCTION ET PRINCIPE
L'utilisation de produits de contrôle de la qualité est indiquée pour évaluer de façon objective la précision des méthodes et des techniques utilisées et fait partie intégrante des bonnes pratiques de laboratoire. Deux concentrations sont disponibles afin de permettre un contrôle de la qualité sur l'ensemble de la plage de valeurs cliniques.

Pour les clients en Allemagne : Des produits de contrôle de qualité sont nécessaires pour l'évaluation des performances de laboratoire comme décrit dans la « Directive pour la garantie de la qualité des tests médicaux de laboratoire selon l'Association Médicale Allemande » (règlement de Rili-BÄK).

RÉACTIF
Ce produit est préparé à partir d'urine humaine à laquelle ont été ajoutés des érythrocytes humains, des leucocytes simulés, des constituants d'origine animale, des produits chimiques, des agents conservateurs et des stabilisants. Le contrôle est fourni sous forme liquide pour un emploi plus aisé.

CONSERVATION ET STABILITÉ
Ce produit restera stable jusqu'à la date de péremption en flacon non ouvert et conservé entre 2 et 8°C. Une fois contrôle ouvert, tous les analytes sont stables pendant 30 jours s'ils sont conservés bien bouchés entre 2 et 25°C. Ce produit ne doit jamais être congelé.

Ce produit est expédié réfrigéré.

MODE OPÉRATOIRE
Ce produit doit être traité comme les échantillons de patients, en respectant les instructions accompagnant l'appareil, le kit ou le réactif utilisé.

Avant utilisation, amener le contrôle à la température ambiante (entre 18 et 25°C) et homogénéiser le produit en agitant plusieurs fois le flacon. Après chaque utilisation, remettre rapidement le bouchon ou la fermeture du bouchon compte-gouttes et conserver entre 2 et 25°C.

Tout déchet doit être éliminé conformément aux réglementations en vigueur dans le laboratoire pour le traitement des déchets. Si le conditionnement est endommagé, contactez votre service technique Bio-Rad local.

INSTRUCTIONS POUR LE BOUCHON COMPTE-GOUTTES
1. Avec précaution, enlever le capuchon à vis et le bouchon du flacon.
2. Fixer solidement le bouchon compte-gouttes sur le dessus du flacon en vissant le capuchon à vis d'origine sur le bouchon compte-gouttes.
3. Homogénéiser le produit en agitant plusieurs fois le flacon.
4. Retirer la fermeture du bouchon compte-gouttes.
5. En tenant une bandelette de test d'urine, appuyer légèrement sur les côtés du bouchon compte-gouttes. Déposer l'échantillon de contrôle sur toutes les plaques de réactifs, en saturant soigneusement chaque plaque. Ne pas aspirer le contrôle restant à l'intérieur du flacon.
6. Essuyer l'extrémité du bouchon compte-gouttes et reboucher en utilisant la fermeture en veillant à ne pas contaminer le niveau 1 en utilisant la fermeture du niveau 2.
7. Conserver à nouveau le flacon entre 2 et 25 °C.
8. Utiliser un nouveau bouchon compte-gouttes avec chaque nouveau flacon de contrôle.

LIMITES
1. Ne pas utiliser ce produit après la date de péremption.
2. En cas de contamination microbienne ou de trouble excessif du produit, éliminer le flacon.
3. Ce produit n'est pas conçu pour être utilisé comme étalon.
4. Ce produit contient de la gentamicine. Suivre les instructions fournies par les fabricants de réactif et/ou du système de test pour les échantillons contenant de la gentamincine.

DÉTERMINATION DES VALEURS
Les résultats indiqués sur cette notice ont été déterminés à partir d'analyses répétées et concernent spécifiquement ce lot de produit. Les essais indiqués ont été réalisés par le fabricant et/ou par des laboratoires indépendants à l'aide de réactifs acceptés par le fabricant et sur un échantillonnage représentatif de ce lot de contrôle. Les variations dans le temps et entre laboratoires peuvent être dues à des différences de méthodes, d'appareils et de réactifs employés par chaque laboratoire ou à des modifications de la méthode d'analyse employée par le fabricant. Il est recommandé à chaque laboratoire de n'utiliser les valeurs fournies qu'à titre indicatif et d'établir ses propres paramètres de précision.

Consulter le site *www.qcnet.com* pour obtenir une mise à jour de la notice.

CARACTÉRISTIQUES
Ce produit est un liquide stabilisé fabriqué selon des normes rigoureuses de contrôle de la qualité. Pour obtenir des résultats reproductibles d'un flacon à l'autre, le contrôle doit être convenablement conservé et manipulé, tel que décrit dans cette notice.

Fournitures en option
Carte RFID (jointe) : Se reporter au Manuel de l'utilisateur Roche pour obtenir le mode d'emploi.

Embouts distributeurs pour flacons de contrôle à bouchon vissé (100/paquet) Article n° 987000 (disponibles séparément)

ITALIANO

USO PREVISTO
Il Liquichek Urinalysis Control è un controllo di qualità su urine, dosato, formulato per monitorare la precisione delle procedure di analisi sui test urinari per gli analiti elencati nel presente inserto.

SOMMARIO E PRINCIPIO
L'uso di materiali per il controllo di qualità è indicato come valutazione oggettiva della precisione dei metodi e delle tecniche in uso e costituisce parte integrante delle buone pratiche di laboratorio. Per permettere di controllare le prestazioni nell'ambito di tutto l'intervallo clinico sono disponibili due livelli di controllo.

Per i clienti in Germania: si richiedono materiali per il controllo della qualità per la valutazione delle prestazioni del laboratorio, come descritto nel documento "Linee guida per la garanzia della qualità degli esami svolti nei laboratori medici in conformità ai requisiti dell'Associazione Medica Tedesca" (Normativa Rili-BÄK).

REATTIVO
Questo prodotto è stato preparato da urina umana con aggiunta di eritrociti umani, leucociti simulati, componenti di origine animale, sostanze chimiche, conservanti e stabilizzanti. Il controllo viene fornito in forma liquida per una maggiore praticità.

CONSERVAZIONE E STABILITÀ
Questo prodotto è stabile fino alla data di scadenza quando viene conservato, non aperto, a 2-8°C. Una volta aperto, tutti gli analiti sono stabili per 30 giorni quando il controllo è conservato, ben chiuso, a 2-25°C. Questo prodotto non deve essere mai congelato.

Il prodotto viene spedito refrigerato.

PROCEDURA
Questo prodotto deve essere trattato allo stesso modo dei campioni in esame ed usato secondo le istruzioni che accompagnano lo strumento, il kit o il reattivo in uso.

Prima dell'uso, lasciare riposare il controllo a temperatura ambiente (18-25°C) e capovolgere delicatamente il flacone diverse volte per garantire l'omogeneità del contenuto. Dopo ogni uso, chiudere immediatamente con il tappo o con il contagocce e conservare il prodotto a 2-25°C.

Eliminare eventuali materiali residui nel rispetto delle norme locali sullo smaltimento dei rifiuti. Nel caso di danni alla confezione, contattare gli uffici Bio-Rad o l'agente di zona.

ISTRUZIONI PER IL CONTAGOCCE
1. Togliere con cura la chiusura a vite ed il tappo del flacone.
2. Inserire bene il contagocce sulla sommità del flacone stringendo la chiusura a vite originaria sopra il contagocce.
3. Capovolgere il flacone diverse volte per garantire l'omogeneità del contenuto.
4. Togliere la chiusura dal contagocce.
5. Tenendo la striscia del test delle urine, premere delicatamente i lati del contagocce. Distribuire il campione di controllo su tutte le aree di reazione, saturando completamente ciascuna di esse. Non aspirare di nuovo il controllo nel flacone.
6. Pulire la punta del contagocce e richiuderlo, facendo attenzione a non scambiare la chiusura del livello 1 con quella del livello 2.
7. Riportare il flacone a temperature comprese fra 2 e 25 °C.
8. Usare un nuovo contagocce per ogni nuovo flacone di controllo.

LIMITI
1. Questo prodotto non deve essere usato dopo la data di scadenza.
2. In caso di evidente contaminazione microbica o di eccessiva torbidezza nel prodotto, eliminare il flacone.
3. Questo prodotto non è concepito per l'uso come standard di riferimento.
4. Questo prodotto contiene gentamicina. Per i campioni contenenti gentamicina, attenersi alle istruzioni fornite dai produttori del reattivo e/o del sistema di analisi.

ASSEGNAZIONE DEI VALORI
I valori riportati in questo inserto sono il risultato di analisi in replicato e sono specifici per questo lotto di prodotto. Le analisi elencate sono state effettuate dal produttore e/o da laboratori indipendenti utilizzando reagenti forniti dal produttore ed una campionatura rappresentativa di questo lotto di controllo. Le variazioni nel tempo e tra laboratori possono essere causate da differenze nelle metodologie, nelle strumentazioni o nei reattivi di ogni laboratorio, o da modifiche metodologiche dei produttori dei reattivi. Ogni laboratorio dovrebbe utilizzare i valori forniti solo come guida e dovrebbe stabilire i propri parametri di precisione.

Consultare il sito *www.qcnet.it* per informazioni sull'aggiornamento dell'inserto.

CARATTERISTICHE
Questo è un prodotto liquido stabilizzato preparato sotto rigidi controlli standard di qualità. Per ottenere una consistente uniformità di risultati da flacone a flacone, si raccomanda una corretta conservazione e un corretto uso, come descritto.

Materiale opzionale
Scheda RFID (allegata): per le istruzioni per l'uso, consultare il Manuale operativo Roche.

Dispensatori per flaconi con tappo a vite (100/confezione) Articolo n. 987000 (disponibili separatamente)

ESPAÑOL

USO INTENCIONADO
Liquichek Urinalysis Control tiene un uso intencionado como orina valorada para el control de la calidad y con el fin de supervisar la precisión de los procedimientos de análisis de orina y para los analitos que se enumeran en este prospecto.

INTRODUCCIÓN Y PRINCIPIO
El uso de materiales para el control de la calidad está indicado para la evaluación objetiva de la precisión de los métodos y las técnicas en uso, y forma parte integral de las buenas prácticas del laboratorio. Existen dos niveles de control para permitir supervisar el funcionamiento dentro del rango clínico.

Para los clientes en Alemania: Para evaluar el funcionamiento del laboratorio es necesario material para el control de la calidad, tal como se describe en la "Directriz para el control de la calidad de los exámenes de laboratorios médicos según la Asociación alemana de médicos" (directriz Rili-BÄK).

REACTIVOS
Este producto está preparado a partir de orina humana a la que se añaden eritrocitos de origen humano, leucocitos artificiales, constituyentes de origen animal, sustancias químicas, conservantes y estabilizadores. El control se suministra líquido para mayor comodidad.

CONSERVACIÓN Y ESTABILIDAD
Este producto permanecerá estable hasta la fecha de caducidad, siempre que esté almacenado sin abrir a una temperatura entre 2 y 8 °C. Una vez abierto, todos los analitos permanecerán estables durante 30 días si se conservan cerrados herméticamente y a una temperatura entre 2 y 25 °C. El producto nunca debe congelarse.

Este producto se transporta refrigerado.

PROCEDIMIENTO
Este producto debe tratarse de la misma forma que las muestras de pacientes y debe ser ensayado conforme a las instrucciones incluidas con el instrumento, kit o reactivos utilizados.

Antes del muestreo, deje que el control alcance la temperatura ambiente (entre 18 y 25 °C) e invierta el vial con suavidad para garantizar su homogeneidad. Tras cada uso, ciérrelo inmediatamente con el tapón o el cierre del tapón gotero y consérvelo de nuevo entre 2 y 25 °C.

Elimine todo material desechable de acuerdo con las normativas locales vigentes sobre la gestión de residuos. En el caso de que el envoltorio haya sufrido daños, póngase en contacto con la oficina de ventas o con el Servicio técnico local de Bio-Rad.

INSTRUCCIONES DE USO DEL TAPÓN GOTERO
1. Retire cuidadosamente el tapón y la tapa de rosca del vial.
2. Una firmemente el tapón gotero a la parte superior del vial apretando la tapa de rosca original del vial sobre el tapón gotero.
3. Invierta el vial con suavidad para garantizar su homogeneidad.
4. Retire el cierre del tapón gotero.
5. Sosteniendo la tira reactiva de la prueba de orina, apriete suavemente el tapón gotero por los lados. Pase la muestra de control por todas las almohadillas de reactivo, saturando totalmente cada una de ellas. No vuelva a introducir el control en el vial por aspiración.
6. Limpie el extremo del tapón gotero y vuelva a cerrarlo asegurándose de no contaminar el nivel 1 utilizando el cierre del nivel 2.
7. Conserve el vial de nuevo entre 2 y 25 °C.
8. Con cada nuevo vial de control debe utilizarse un nuevo tapón gotero.

LIMITACIONES
1. Este producto no debe utilizarse después de la fecha de caducidad.
2. Si hubiese indicios de contaminación microbiana o exceso de turbidez en el producto, deseche el vial.
3. Este producto no está previsto para ser utilizado como estándar.
4. Este producto contiene gentamicina. Siga las instrucciones facilitadas por los fabricantes del reactivo o sistema de análisis para las muestras que contienen gentamicina.

ASIGNACIÓN DE VALORES
Los resultados que figuran en este prospecto se obtuvieron a partir de la replicación de análisis y son específicos de este lote de producto. Las pruebas fueron realizadas por el fabricante o por laboratorios independientes que utilizaron reactivos admitidos por el fabricante y una muestra representativa de este lote de control. Las variaciones a lo largo del tiempo y entre laboratorios pueden deberse a diferencias en las técnicas del laboratorio, su instrumental y sus reactivos, o a modificaciones introducidas en el método de medida del fabricante. Cada laboratorio debe utilizar los resultados indicados sólo como referencia, y establecer sus propios parámetros de precisión.

Puede consultar las actualizaciones de prospectos en la página web *www.qcnet.com*.

CARACTERÍSTICAS ESPECÍFICAS DE FUNCIONAMIENTO
Éste es un producto líquido estabilizado que ha sido fabricado según las más estrictas normas de control de la calidad. Para obtener valores de ensayo coherentes entre viales, será necesario almacenar y manipular el control según se indica.

Suministros opcionales
Tarjeta RFID (adjunta): Consulte las instrucciones de uso en el manual del operador de Roche (Roche Operator's Manual).

Tapones goteros para viales de tapa de rosca (100/paquete) - Nº de referencia 987000 (disponibles por separado)

BIO-RAD Liquichek™ Urinalysis Control, Levels 1 and 2

PORTUGUÊS

UTILIZAÇÃO
O Liquichek Urinalysis Control destina-se a ser utilizado como urina de controlo da qualidade ensaiada para controlar a precisão dos procedimentos de análise de urina para os analitos listados neste folheto informativo.

SUMÁRIO E PRINCÍPIO
A utilização de materiais de controlo da qualidade é indicada como uma avaliação objectiva da precisão de métodos e técnicas aplicados e é parte integrante das boas práticas laboratoriais. Encontram-se disponíveis dois níveis de controlo para permitir aferir o desempenho dentro dos limites clínicos.

Para os clientes na Alemanha: A utilização de materiais de controlo da qualidade é necessária para avaliação do desempenho laboratorial, conforme descrito no documento "Directriz para o Controlo de Qualidade de Exames Médicos Laboratoriais de acordo com a Associação Médica Alemã" (regulamento Rili-BÄK).

REAGENTE
Este produto é preparado a partir de urina humana acrescida de eritrócitos humanos, leucócitos simulados, constituintes de origem animal, substâncias químicas, conservantes e estabilizadores. O controlo é fornecido sob forma líquida para maior conveniência.

ARMAZENAMENTO E ESTABILIDADE
Este produto permanecerá estável até ao fim do prazo de validade desde que seja armazenado por abrir a uma temperatura de 2 a 8°C. Uma vez aberto, todos os analitos permanecerão estáveis durante 30 dias, desde que armazenados com a tampa firmemente apertada a uma temperatura de 2 a 25°C. Este produto nunca deve ser congelado.

Este produto é enviado em condições de refrigeração.

PROCEDIMENTO
Este produto deve ser tratado da mesma forma que as amostras de pacientes e utilizado de acordo com as instruções que acompanham o instrumento, dispositivo ou reagente que está a ser utilizado.

Antes de efectuar a recolha da amostra, permita que o controlo atinja a temperatura ambiente (18 a 25°C) e inverta o frasco várias vezes para assegurar a homogeneidade. Após cada utilização, reponha imediatamente a tampa interna ou o conta-gotas e volte a armazenar a uma temperatura de 2 a 25°C.

Elimine todos os materiais fora de uso de acordo com as disposições locais em vigor para a eliminação de resíduos biológicos. Na eventualidade de observar danos na embalagem, contacte a Bio-Rad Laboratories.

INSTRUÇÕES PARA OS CONTA-GOTAS
1. Retire cuidadosamente a tampa de rosca e a tampa interna.
2. Fixe o conta-gotas ao frasco apertando a tampa de rosca original do frasco por cima do conta-gotas.
3. Inverta o frasco várias vezes para assegurar a homogeneidade.
4. Retire a ponta do conta-gotas.
5. Segurando a tira de análise de urina, pressione ligeiramente os lados do conta-gotas. Passe a amostra do controlo por todas as zonas reagentes, saturando por completo cada zona. Não aspire o controlo novamente para dentro do frasco.
6. Limpe a ponta do conta-gotas e volte a colocá-la, tendo o cuidado de não contaminar o nível 1 com a ponta do nível 2.
7. Volte a colocar o frasco a uma temperatura de 2 a 25°C.
8. Deve ser utilizado um novo conta-gotas com cada novo frasco de controlo.

LIMITAÇÕES
1. Este produto não deve ser utilizado após o fim do prazo de validade.
2. Se existir evidência de contaminação microbiana ou turvação excessiva no produto, elimine o frasco.
3. Este produto não deve ser utilizado como padrão.
4. Este produto contém gentamicina. Siga as instruções fornecidas pelo fabricante do reagente e/ou sistema de testes para amostras que contenham gentamicina.

VALORIZAÇÕES
Os resultados impressos neste folheto derivam de análises repetidas e são específicos para este lote do produto. Os testes listados foram executados pelo fabricante e/ou por laboratórios independentes utilizando reagentes suportados pelo fabricante e uma amostra representativa deste lote de controlo. Variações ao longo do tempo e entre laboratórios podem dever-se a diferenças de técnicas, instrumentos ou reagentes, ou a modificações nas técnicas de teste pelo fabricante. Cada laboratório deve utilizar os resultados fornecidos apenas como uma referência e estabelecer os seus próprios parâmetros de precisão.

Consulte o site *www.qcnet.com* para obter informações sobre actualizações de folhetos informativos.

CARACTERÍSTICAS ESPECÍFICAS DE DESEMPENHO
Este produto é um produto líquido estabilizado, fabricado de acordo com os mais rígidos padrões de controlo da qualidade. Para obter valorizações consistentes de frasco para frasco, o controlo deve ser manuseado e armazenado de acordo com o descrito.

Consumíveis opcionais
Cartão RFID (anexo): Consulte as instruções de utilização no Manual do Operador da Roche.

Conta-gotas para tampas de rosca (100/embalagem) Artigo n.º 987000 (vendido à parte)

SVENSKA

AVSEDD ANVÄNDNING
Liquichek Urinalysis Control är en analyserad kvalitetskontrollurin avsedd för kontroll av precisionen i testförfaranden för urinanalys, för de analyter som anges i denna bipacksedel.

SAMMANFATTNING OCH PRINCIP
Användning av kvalitetskontrollmaterial är indicerad för objektiv utvärdering av precisionen i använda metoder och tekniker och ingår i god laboratoriepraxis. Två kontrollnivåer finns tillgängliga för kontroll av prestandan inom det kliniska mätområdet.

För kunder i Tyskland: Kvalitetskontrollmaterial krävs för utvärdering av laboratoriers prestanda, enligt beskrivningen i "Riktlinjer för kvalitetssäkring av utvärdering av medicinska laboratorier enligt det tyska läkarförbundet" (Rili-BÄK-bestämmelsen).

REAGENS
Denna produkt är framställd av human urin med tillsats av humana erytrocyter, simulerade leukocyter, beståndsdelar av animaliskt ursprung, kemikalier, konserveringsmedel och stabiliseringsmedel. Kontrollsubstansen tillhandahålls i praktisk vätskeform.

FÖRVARING OCH STABILITET
Denna produkt är stabil fram till utgångsdatum vid förvaring i oöppnad förpackning vid 2 till 8°C. När kontrollflaskan har öppnats är alla analyter stabila i 30 dagar om flaskan förvaras väl tillsluten vid 2-25°C. Denna produkt får aldrig frysas.

Produkten levereras med kyltransport.

FÖRFARANDE
Denna produkt skall behandlas på samma sätt som patientprover och användas enligt anvisningarna för de instrument, kit och reagenser som används.

Låt kontrollen uppnå rumstemperatur (18 till 25°C) innan den används och vänd flaskan flera gånger så att innehållet blandas ordentligt. Efter varje användning skall flaskan omedelbart förslutas med propp eller droppock och förvaras enligt anvisningarna i kylförvaring vid 2 – 25°C.

Kasserat material skall hanteras enligt de avfallsbestämmelser som utfärdats av lokala myndigheter. Om förpackningen är skadad, kontakta närmaste Bio-Rad Laboratories försäljningsavdelning eller teknisk serviceavdelning.

ANVISNINGAR FÖR ANVÄNDNING AV KLÄMLOCK
1. Avlägsna försiktigt flaskans skruvlock och propp.
2. Sätt på dropplocket längst upp på flaskan så att den sitter stadigt, genom att dra åt flaskans skruvlock över dropplocket.
3. Vänd flaskan upp och ner flera gånger så att innehållet blandas ordentligt.
4. Ta av skyddet från dropplocket.
5. Håll i teststickan för urin och kläm varligt ihop sidorna på dropplocket. Dra med kontrollen över alla reagensrutorna så att varje ruta genomfuktas ordentligt. Kontrollmaterialet får inte sprutas tillbaka ned i flaskan.
6. Torka av dropplocket och sätt tillbaka skyddet, och var samtidigt noga med att inte kontaminera nivå 1 genom att använda skyddet till nivå 2.
7. Sätt tillbaka flaskan i förvaring vid 2-25 °C.
8. Ett nytt dropplock skall användas till varje ny kontrollflaska.

BEGRÄNSNINGAR
1. Denna produkt skall inte användas efter utgångsdatum.
2. Vid tecken på mikrobiell kontaminering eller om kontrollen är mycket grumlig skall flaskan kasseras.
3. Denna produkt är inte avsedd att användas som en standard.
4. Denna produkt innehåller gentamicin. Följ anvisningarna från reagenstillverkaren och/eller testsystemets tillverkare avseende prover innehållande gentamicin.

NOMINELLA VÄRDEN
De resultat som anges i denna bipacksedel härrör från replikatanalyser och är specifika för denna produktbatch. De angivna testerna har utförts av tillverkaren och/eller oberoende laboratorier med användning av reagens som stöds av tillverkaren och representativa prover av denna kontrollbatch. Variationer över tiden och från laboratorium till laboratorium kan bero på skillnader i laboratorieteknik, instrument och reagenser, eller på modifikationer i tillverkarens testmetoder. Varje enskilt laboratorium bör fastställa sina egna precisionsparametrar och endast använda de angivna resultaten som referens.

Besök *www.qcnet.com* för aktuell bipacksedelsinformation.

SPECIFIKA PRODUKTEGENSKAPER
Denna produkt är en stabiliserad kontroll som framställs enligt strikta kvalitetskontrollstandarder. För reproducerbara analysresultat från flaska till flaska skall kontrollen förvaras och hanteras korrekt, enligt anvisningarna.

Valfritt material
RFID-kort (medföljer): Se användarmanualen från Roche för bruksanvisning.

Dispenseringsspetsar för skruvlock (100/förpackning) Produktnr 987000 (tillgängliga separat)

DANSK

TILSIGTET ANVENDELSE
Liquichek Urinalysis Control er beregnet til anvendelse som en analyseret kvalitetskontrolurin med henblik på overvågning af præcisionen af metoder til urinanalyse for de analytter, der er angivet i indlægssedlen.

RESUMÉ OG PRINCIP
Anvendelsen af kvalitetskontrolmateriale er tilsigtet som en objektiv vurdering af de anvendte metoders og teknikkers præcision og er en integreret del af god laboratoriepraksis. Der findes to kontrolniveauer tilgængelige til overvågning af præstationen inden for det kliniske område.

Til kunder i Tyskland: Kvalitetskontrolmaterialer er nødvendige til vurdering af laboratorieprræstationen som beskrevet i "Retningslinjer for kvalitetssikring for undersøgelser i medicinske laboratorier iht. den tyske lægeforening" (Rili-BÄK-regler).

REAGENS
Dette produkt er fremstillet af human urin tilsat humane erytrocytter, simulerede leukocytter, bestanddele af animalsk oprindelse, kemikalier, konserveringsmidler og stabilisatorer. Kontrolmaterialet leveres i flydende form af praktiske hensyn.

OPBEVARING OG STABILITET
Dette produkt er holdbart til udløbsdatoen ved opbevaring uåbnet ved 2-8°C. Efter åbning vil alle analytter være stabile i 30 dage ved opbevaring med tæt lukket låg ved 2 til 25°C. Dette produkt må aldrig fryses.

Dette produkt forsendes nedkølet.

FREMGANGSMÅDE
Dette produkt skal behandles som patientprøver og anvendes iht. de vejledninger, der følger med det anvendte instrument, reagenskit eller reagens.

Inden analysering skal kontrolmaterialet have stuetemperatur (18-25°C) og vendes forsigtigt flere gange for at sikre homogenitet. Efter hver brug skal låget eller dråbetællerlåget straks sættes på igen, og anbringes ved 2-25°C.

Kasseret materiale skal bortskaffes iht. gældende affaldsregulativer. Hvis emballagen er beskadiget, kontaktes den lokale Bio-Rad Laboratories forhandler eller teknisk service hos Bio-Rad Laboratories.

ANVISNING TIL DRÅBETÆLLERLÅGET
1. Tag forsigtigt ampullens skruelåg og låg af.
2. Sæt dråbetællerlåget på ampullen, så det sidder godt fast, ved at stramme ampullens skruelåg over dråbetællerlåget.
3. Vend ampullen flere gange for at sikre homogenitet.
4. Tag hætten af dråbetællerlåget.
5. Hold fat i teststrimlen til urin, og tryk samtidigt let på siderne af dråbetællerlåget. Før kontrollen langs samtlige reagensfelter, så hvert felt bliver godt gennemfugtet. Kontrolmaterialet må ikke suges tilbage i ampullen.
6. Tør dråbetællerspidsen af, og sæt hætten på. Sørg for ikke at bruge hætten til niveau 2, da dette vil medføre at niveau 1 kontamineres.
7. Anbring hætteglasset ved 2 til 25 °C.
8. Der skal anvendes et nyt dråbetællerlåg til hver ny ampul med kontrolmateriale.

BEGRÆNSNINGER
1. Dette produkt bør ikke anvendes efter udløbsdatoen.
2. Hvis der er tegn på mikrobiel kontaminering i produktet, eller det er meget uklart, skal ampullen kasseres.
3. Dette produkt er ikke beregnet til anvendelse som standard.
4. Dette produkt indeholder gentamicin. Følg instruktionerne fra reagensets og/eller testsystemets producent vedr. prøver, der indeholder gentamicin.

TILDELING AF VÆRDIER
Resultaterne, der er trykt på denne indlægsseddel, er udledt af gentagne analyser og er specifikke for dette produktlot. De angivne analyser blev udført af producenten og/eller uafhængige laboratorier vha. reagenser understøttet af producenten og en repræsentativ prøve af dette lot af kontrolmateriale. Variationer over tid og imellem laboratorier kan skyldes forskellige laboratorieteknikker, instrumenter og reagenser, eller modifikationer i testmetoder fra producentens side. De enkelte laboratorier bør bestemme deres egne præcisionsparametre og kun betragte de medfølgende værdier som vejledende.

Der henvises til *www.qcnet.com* vedr. opdateringer af indlægssedlen.

SPECIFIKKE YDELSESEGENSKABER
Dette produkt er en stabiliseret væske, der er produceret under strenge kvalitetskontrolkrav. Kontrolmaterialet skal opbevares korrekt og håndteres som anvist for at give pålidelige resultater.

Ekstra produkter
RFID-kort (vedlagt): Der henvises til Roche-brugervejledningen for anvisninger i brug.

Dispenserspidser til skruelåg (100 stk./pakke), artikelnr. 987000 (fås separat)

Liquichek™ Urinalysis Control, Levels 1 and 2

TÜRKÇE

KULLANIM AMACI

Liquichek Urinalysis Control, idrar analizi test prosedürlerinin bu prospektüste listelenen analitler için kesinliğinin takip edilmesi amacıyla, değerleri bilinen bir kalite kontrol idrarı olarak kullanılması içindir.

ÖZET VE PRENSİP

Kalite kontrol materyallerinin kullanılması, çalışılan yöntemlerin ve tekniklerin kesinliği ile ilgili objektif bir değerlendirme yapılması içindir ve iyi laboratuvar uygulamalarının ayrılmaz bir parçasıdır. Klinik aralıkta performansın takip edilmesi için iki seviye kontrol mevcuttur.

Almanya'daki müşteriler için: Laboratuvar performansının, "Alman Tıp Derneği'nin İzinde Tıbbi Laboratuvar İncelemeleri Kalite Kontrol Kılavuzu" (Rili-BÄK düzenlemesi) kapsamında açıklanan şekilde değerlendirilmesi için, kalite kontrol malzemeleri gereklidir.

REAKTİF

Bu ürün, insan eritrositleri, simule edilmiş lökositler, hayvan kaynaklı bileşenler, kimyasallar, koruyucu maddeler ve stabilizatörlerin eklendiği insan idrarından hazırlanmaktadır. Kontrol kolay kullanım amacıyla sıvı formda verilmektedir.

SAKLAMA VE STABİLİTE

Bu ürün açılmadan 2 ila 8°C arasında saklandığında son kullanma tarihine kadar stabildir. Kontrol açılıp sıkıca kapatılarak saklandığında, tüm analitler 2 ila 25°C arasında 30 gün stabildir. Bu ürün hiçbir zaman dondurulmamalıdır.

Bu ürün soğutulmuş koşullar altında sevk edilir.

PROSEDÜR

Bu ürün hasta örnekleri ile aynı muameleye tabi tutulmalıdır ve kullanılmakta olan cihaz, kit veya reaktif ile birlikte verilen talimatlara uygun olarak çalışılmalıdır.

Numune almadan önce kontrolün oda sıcaklığına (18 ila 25°C) gelmesini bekleyin ve homojen hale gelmesini sağlamak için flakonu birkaç kere ters çevirin. Her kullanımdan sonra kapağını kapatın veya damlalığı takın ve 2 ila 25°C arasında saklayın.

Herhangi bir atık malzemeyi yerel atık yönetimi yetkililerinin gereklerine uygun olarak atın. Ambalajda hasar olması durumunda, Bio-Rad Laboratories Satış Ofisi veya Bio-Rad Laboratories Teknik Servisi ile irtibata geçin.

DAMLALIK TALİMATLARI

1. Flakonun vidalı başlığını ve kapağını dikkatle çıkarın.
2. Orijinal flakonun vidalı kapağını damlalığın üzerine sıkıştırarak damlalığı flakonun üst kısmına sağlamca takın.
3. Homojen hale gelmesini sağlamak için flakonu birkaç kere ters çevirin.
4. Damlalığın kapağını çıkarın.
5. İdrar test stribini tutarken, damlalığın yanlarından yavaşça bastırın. Kontrol numunesini reaktif pedlerinin her yerine ve her bir pedi iyice ıslatarak uygulayın. Kontrolü flakonun içine geri aspire etmeyin.
6. Damlalığı silin ve seviye 1'i seviye 2'nin kapağını kullanarak kontamine etmediğinizden emin olarak kapağını kapatın.
7. Flakonu 2 ila 25°C arasında saklamaya devam edin.
8. Her yeni kontrol flakonunda yeni damlalık kullanılmalıdır.

SINIRLAMALAR

1. Bu ürün son kullanma tarihinden sonra kullanılmamalıdır.
2. Üründe mikrobiyal kontaminasyona veya aşırı türbiditeye dair bir gösterge varsa, flakonu atın.
3. Bu ürünün bir standart olarak kullanılması amaçlanmamıştır.
4. Bu ürün gentamisin içerir. Reaktif ve/veya test sistemi üreticilerinin gentamisin içeren numuneler için verdikleri talimatları takip edin.

DEĞERLERİN TAYİN EDİLMESİ

Bu prospektüste yazılı olan sonuçlar tekrar tekrar yapılan analizlerden elde edilmiştir ve ürünün bu lotuna özgüdür. Listelenen testler, üreticinin sağladığı reaktifler ve kontrolün bu lotunun temsili bir numunesi kullanılarak üretici ve/veya bağımsız laboratuvarlar tarafından gerçekleştirilmiştir. Zaman içerisindeki ve laboratuvarlar arasındaki değişiklikler laboratuvar tekniği, cihaz ve reaktiflerdeki farklılıklar veya üreticinin test yöntemindeki modifikasyonları neden olabilir. Her laboratuvar sadece referans olarak sağlanan sonuçları kullanmalı ve kendi kesinlik parametrelerini belirlemelidir.

Güncel prospektüs bilgileri için *www.qcnet.com* adresine bakın.

SPESİFİK PERFORMANS ÖZELLİKLERİ

Bu ürün, sıkı kalite kontrol standartları altında üretilmiş stabilize bir sıvı üründür. Flakondan flakona tutarlı test değerleri elde etmek için kontrolün belirtilen şekillerde saklanması ve kullanılması gerekmektedir.

İsteğe bağlı Malzemeler

RFID Kartı (ektedir): Kullanım talimatları için Roche Kullanıcı Kılavuzuna bakın.

Vidalı kapaklar için damlalıklar (100/paket) Parça No. 987000 (ayrı olarak mevcuttur)

DİPNOTLAR

(1) Bazı analitlerde tipik olmayan bir renk gözlenebilir. Sonuçlar reaksiyon yoğunluklarına dayanmaktadır.
(2) Tipik olmayan renk gözlenmiştir.
(3) Reaksiyon görsel olarak pozitiftir. Cihaz okuma değeri tipik olmayan renkten dolayı negatiftir.
(4) Duyarlılığı ≥ 10 mIU/mL olan diğer test kitlerinde.
(5) Roche damlalıkların kullanılmasındansa striplerin batırılmasını önermektedir.
(6) Mikroskopik analizde bakteriler mevcut olabilir. Beklenen değerler veya stabilite için herhangi bir öneride bulunulmamıştır.
(7) lpf = düşük güç alanı;
hpf = yüksek güç alanı.
(8) Sonuçlar KOVA Standardize İdrar Analizi Sisteminin üretici talimatları takip edilerek elde edilmiştir.
(9) İnsan idrarı matriksinden dolayı bu ürün bilinen diğer idrar kristallerinden ve kalıntısından da içerebilir ve bunlar için beklenen performans veya stabilite için herhangi bir öneride bulunulmamıştır.
(10) Bu ürün Sistin kristalleri içerir.
§ Bu test ile ilgili ortalama değerlerin ve kabul edilebilir aralıkların belirlenmesi için gereken veriler tayine sınırlı sayıda katılımdan dolayı sağlanamamıştır. Merkeziniz bu test ile ilgili Değer Tayini Programına katılmayı düşünüyorsa, lütfen yerel Bio-Rad Satış veya Teknik Servis Grubu ile irtibata geçin.
❖ SADECE ULUSLARARASI KULLANIM - Aşağıdaki bölüm Birleşik Devletlerde diagnostik kullanım için mevcut olmayan yöntemlere dair veriler içermektedir.

日本語

序論

Liquichek Urinalysis Control(リクイチェック尿検査用コントロール)は、本インサートに記載されている検査成分を対象とした尿検査における精度管理のための参考値付きコントロール尿です。

概要と意義

測定法や測定技術の精度を客観的に評価するために精度管理物質が使用されます。精度管理物質は、検査室の臨床試験を管理する上で不可欠です。本製品は、臨床的に有意義な2濃度のコントロール尿として提供されています。
ドイツのお客様向け:精度管理製品は、「ドイツ医師会による臨床検査施設の検査の品質管理に関するガイドライン」(Rili-BÄK規制)に記載されているとおり、各施設の性能を評価するために必要とされています。

試薬

本製品はヒト尿をベースとして、ヒト赤血球、擬似白血球、動物由来成分、化学物質、防腐剤、および安定剤を添加して調製されています。また、使用しやすい液状タイプです。

貯法および安定性

未開封のまま2~8℃で保存した場合、有効期限まで安定です。開封後に密栓し2~25℃で保存した場合、全成分30日間安定です。本製品の凍結保存は避けてください。

使用方法

本製品は、患者検体と同様に取り扱い、使用する測定機器やキット、試薬などの指示に従ってご使用ください。
使用前に、本製品を室温(18~25℃)に戻し、溶液が均一になるようにバイアルを数回転倒混和します。使用後は、直ちに密栓するか、ディスペンサーチップの留めを締め、再度2~25℃で保存してください。
廃棄する場合は、国や各自治体の指示に従って廃棄してください。パッケージに損傷のある場合は、バイオ・ラッド　ラボラトリーズ(株)へご連絡ください。

ディスペンサーチップの取扱い方法

1. バイアルからキャップとゴム栓を慎重に取り外します。
2. ディスペンサーチップの上から、バイアルに付いているキャップを締め、ディスペンサーチップをしっかりとバイアルに取り付けます。
3. 溶液が均一になるようにバイアルを数回軽く転倒混和します。
4. ディスペンサーチップの留めを外します。
5. 尿検査用ストリップを持ち、ディスペンサーチップの両側を軽く押します。本製品サンプルを全ての試薬パッドに抽出し、各パッドに十分染み込ませます。本製品をバイアルに吸引して戻さないでください。
6. ディスペンサーチップの先を拭き、レベル2とレベル1の留めが交差汚染しないように蓋をします。
7. バイアルは、再度2~25℃で保存してください。
8. コントロールバイアルには、毎回新しいディスペンサーチップを使用してください。

使用上の注意

1. 有効期限の過ぎた本製品は、使用しないでください。
2. 本製品に微生物の混入や顕著な混濁が認められた場合は、バイアルを廃棄してください。
3. 本製品を標準物質として使用しないでください。
4. 本製品はゲンタマイシンを含有しています。ゲンタマイシンを含有するサンプルの検査には、システムメーカーまたは試薬メーカーが提供する取扱説明書に従ってください。

平均値および範囲

本インサートに記載されている測定結果は、複数の検査データより得られたもので、本ロット特有の値です。記載されている値は、試薬メーカーまたは外部の検査施設により、本ロットの代表サンプルとメーカーの試薬を用いて得られた値です。範囲には測定方法、測定技術、機器および試薬間の変動が含まれています。測定成績は、それぞれの機器、試薬の状態に基づくため、各施設で独自の精度管理に関するパラメーターを設定し、本インサートに記載した数値は参考としてご使用になることをお勧めします。
インサート改訂情報については、http://www.qcnet.com/JP を参照してください。

性能特性

本製品は、厳しい品質管理基準に従って製造された、優れた安定性を有する液状の製品です。バイアル間での測定値の変動を防ぐために、前述したように適切に保存し取り扱ってください。

付属品(オプション)

RFIDカード(同梱):製品説明書は、Roche社のオペレーターズマニュアルを参照してください。
スクーザーキャップ用ディスペンサーチップ(100個/包) 商品コード12043(別売)

精度管理用

脚注

(1) 成分によっては通常みられない色を示すことがあります。検査結果は、反応の強度に基づき得られた値です。
(2) 通常みられない色を示します。
(3) 反応は、視覚ではっきり確認できます。機器の測定値は、通常みられない色のため陰性になります。
(4) 10mIU/mL以上の感受性を有するその他の試薬キットを使用してください。
(5) Roche社は、ディスペンサーチップを使用する替わりにストリップを浸すことをお勧めしています。
(6) 顕微鏡分析で細菌を確認できる場合があります。この検査成分の値や安定性に関しては、データがありません。
(7) lpf = 低倍率視野
hpf = 高倍率視野
(8) 検査結果は、標準尿検査用KOVA Systemについてのメーカーが提供する取扱説明書に従って得られた値です。
(9) ヒト尿ベースのため、一般によく見られる尿結晶および組織片を含有している可能性があります。尿結晶および組織片に関しては参考値や安定性についてのデータはありません。
(10) 本製品はシスチン結晶を含有しています。
§ データ取りにご協力いただいた供与者が少なかったため、本測定の平均値と許容範囲を設定するために十分なデータを得ることができません。本測定の参考値取りにご協力いただける場合は、バイオ・ラッドラボラトリーズ(株)へご連絡ください。
❖ 米国以外での使用のみ:次の項には、米国における検査結果には適用されない測定法のデータが含まれています。

問い合わせ先

製品に関するお問い合わせ・ご質問等はこちらのフリーダイヤルをご利用ください。
0120-925046(平日9:00~17:30)

WARNING

Warnung // Attention // Avvertenza // Precauciones // Aviso // Varning // Advarsel // Uyarı // 感染注意

ENGLISH

Biological source material. Treat as potentially infectious.

The serum from each donor contributing urine for this product was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2. This product may also contain other human source material for which there are no approved tests. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

Contains 5-chloro-2-methyl-2H-isothiazol-3-one.

Hazard (H) and Precautionary (P) Statements

H317 May cause an allergic skin reaction. **P261** Avoid breathing dust/fume/gas/mist/vapours/spray. **P280** Wear protective gloves/protective clothing/eye protection/face protection. **P272** Contaminated work clothing should not be allowed out of the workplace. **P363** Wash contaminated clothing before reuse. **P333+P313** If skin irritation or rash occurs: Get medical advice/attention. **P302+P352** IF ON SKIN: Wash with plenty of soap and water.

Safety Data Sheet (SDS) available for professional users on *www.bio-rad.com*.

DEUTSCH

Material biologischer Herkunft. Als potenziell infektiös zu behandeln.

Das Serum jedes Spenders, der Urin für diese Kontrolle gespendet hat, wurde mit von der amerikanischen Arzneimittelbehörde FDA (Food and Drug Administration) zugelassenen Methoden auf Hepatitis-B-Oberflächen-Antigen (HBsAg), Antikörper gegen Hepatitis C (HCV) und Antikörper gegen HIV-1/HIV-2 getestet und für nicht reaktiv befunden. Das Produkt enthält unter Umständen andere Bestandteile humanen Ursprungs, für die keine zugelassenen Tests existieren. In Übereinstimmung mit der guten Laborpraxis sollten alle Materialien humanen Ursprungs als potenziell infektiös betrachtet und mit der gleichen Sorgfalt wie Patientenproben behandelt werden.

Enthält 5-Chlor-2-methyl-2H-isothiazol-3-on.

H- und P-Sätze zu Gefährdungen und Vorsichtsmaßnahmen

H317 Kann allergische Hautreaktionen verursachen. **P261** Einatmen von Staub / Rauch / Gas / -Nebel / Dampf / Aerosol vermeiden. **P280** Schutzhandschuhe / Schutzkleidung / Augenschutz / Gesichtsschutz tragen. **P272** Kontaminierte Arbeitskleidung nicht außerhalb des Arbeitsplatzes tragen. **P363** Kontaminierte Kleidung vor erneutem Tragen waschen. **P333+P313** Bei Hautreizung oder -ausschlag: Ärztlichen Rat einholen/ärztliche Hilfe hinzuziehen. **P302+P352** BEI KONTAKT MIT DER HAUT: Mit viel Wasser und Seife waschen.

Sicherheitsdatenblätter (SDB) stehen Ihnen im Internet unter *www.bio-rad.com* zur Verfügung.

FRANÇAIS

Produit d'origine biologique. À considérer comme potentiellement infectieux.

Le sérum de chaque donneur d'urine a été analysé à l'aide de méthodes approuvées par la FDA (Food and Drug Administration, U.S.A.) et a présenté des résultats négatifs pour l'antigène de surface de l'hépatite B (AgHBS), et les anticorps de l'hépatite C (VHC) et du VIH-1/VIH-2. Il est possible que ce produit contienne d'autres substances d'origine humaine pour lesquelles il n'existe pas de test agréé. Conformément aux bonnes pratiques de laboratoire, toute substance d'origine humaine doit être considérée comme potentiellement infectieuse et manipulée avec les mêmes précautions que les échantillons provenant de patients.

Contient du 5-chloro-2-méthyl-2H-isothiazol-3-one.

Mentions de dangers (H) et conseils de prudence (P)

H317 Peut provoquer une allergie cutanée. **P261** Éviter de respirer les poussières / fumées / gaz / brouillards / vapeurs / aérosols. **P280** Porter des gants de protection / des vêtements de protection / un équipement de protection des yeux / du visage. **P272** Les vêtements de travail contaminés ne devraient pas sortir du lieu de travail. **P363** Laver les vêtements contaminés avant réutilisation. **P333+P313** En cas d'irritation ou d'éruption cutanée: consulter un médecin. **P302+P352** EN CAS DE CONTACT AVEC LA PEAU: laver abondamment à l'eau et au savon.

Une fiche de sécurité (SDS) est à disposition des utilisateurs professionnels sur le site *www.bio-rad.com*.

ITALIANO

Materiale di origine biologica. Trattare come potenzialmente infettivo.

Il siero di ciascun donatore di urina utilizzata per preparare questo prodotto è stato testato mediante metodi approvati dalla FDA ed è risultato non reattivo per l'antigene di superficie dell'epatite B (HBsAg), l'anticorpo contro l'epatite C (HCV) e l'anticorpo contro l'HIV-1/HIV-2. Questo prodotto può anche contenere altro materiale di origine umana per il quale non esistono procedure di dosaggio approvate. Secondo le buone pratiche di laboratorio, tutti i materiali di origine umana devono essere considerati potenzialmente infettivi, perciò si raccomanda di trattare questo prodotto con le medesime precauzioni adottate per i campioni dei pazienti.

Contiene 5-cloro-2-metil-2H-isotiazol-3-one.

Dichiarazioni di Rischio (H) e Precauzionali (P)

H317 Può provocare una reazione allergica cutanea. **P261** Evitare di respirare la polvere / i fumi / i gas / la nebbia / i vapori / gli aerosol. **P280** Indossare guanti / indumenti protettivi / Proteggere gli occhi / il viso. **P272** Gli indumenti da lavoro contaminati non devono essere portati fuori dal luogo di lavoro. **P363** Lavare gli indumenti contaminati prima di indossarli nuovamente. **P333+P313** In caso di irritazione o eruzione della pelle: consultare un medico. **P302+P352** IN CASO DI CONTATTO CON LA PELLE: lavare abbondantemente con acqua e sapone.

Scheda informativa sulla sicurezza (SDS) ad uso professionale disponibile al sito *www.bio-rad.com*.

ESPAÑOL

Material de origen biológico. Manipular como potencialmente infeccioso.

Los sueros de todos los donantes de orina utilizada en la fabricación de este producto se han analizado según métodos de análisis aceptados por la FDA (agencia estadounidense para alimentos y fármacos) y se ha determinado que no reaccionan contra el antígeno superficial de la hepatitis B (HBsAg), el anticuerpo de la hepatitis C (VHC) y el anticuerpo del VIH-1/VIH-2. Este producto puede contener asimismo material de origen humano para el que no existen análisis homologados. De acuerdo con las prácticas de laboratorio correctas, todo material de origen humano se debe considerar potencialmente infeccioso y manipular con las mismas precauciones que las muestras de pacientes.

Contiene 5-cloro-2-metil-dihidro-isotiazol-3-ona.

Indicaciones de peligro (H) y de precaución (P)

H317 Puede provocar una reacción alérgica en la piel. **P261** Evitar respirar el polvo / el humo / el gas / la niebla / los vapores / el aerosol. **P280** Llevar guantes / prendas / gafas / máscara de protección. **P272** Las prendas de trabajo contaminadas no podrán sacarse del lugar de trabajo. **P363** Lavar las prendas contaminadas antes de volver a usarlas. **P333+P313** En caso de irritación o erupción cutánea: Consultar a un médico. **P302+P352** EN CASO DE CONTACTO CON LA PIEL: Lavar con agua y jabón abundantes.

La ficha de datos de seguridad (SDS) está disponible para los usuarios profesionales en *www.bio-rad.com*.

PORTUGUÊS

Material de origem biológica. Tratar como potencialmente infeccioso.

O soro de cada dador cuja urina foi utilizada no fabrico deste produto foi testado pelos métodos aprovados pela FDA (Administração dos Alimentos e Fármacos dos Estados Unidos da América), tendo sido considerado não reactivo em antigénios de superfície da hepatite B (HBsAg), anticorpo da hepatite C (HCV) e anticorpos HIV-1/HIV-2. Este produto também poderá conter outros materiais de origem humana para os quais não existem testes aprovados. De acordo com as boas práticas laboratoriais, todo o material de origem humana deve ser considerado potencialmente infeccioso, pelo que deverá ser manuseado com as mesmas precauções utilizadas com as amostras dos pacientes.

Contém 5-cloro-2-metil-2H-isotiazol-3-ona.

Frases de Perigo (H) e de Prudência (P)

H317 Pode provocar uma reacção alérgica cutânea. **P261** Evitar respirar as poeiras / fumos / gases / névoas / vapores / aerossóis. **P280** Usar luvas de protecção / vestuário de protecção / protecção ocular / protecção facial. **P272** A roupa de trabalho contaminada não pode sair do local de trabalho. **P363** Lavar a roupa contaminada antes de a voltar a usar. **P333+P313** Em caso de irritação ou erupção cutânea: consulte um médico. **P302+P352** SE ENTRAR EM CONTACTO COM A PELE: lavar com sabonete e água abundantes.

Existem fichas de dados de segurança (SDS) disponíveis para os utilizadores profissionais em *www.bio-rad.com*.

SVENSKA

Material av biologiskt ursprung. Skall behandlas som potentiellt infektiöst.

Serumprover från alla urindonatorer till denna produkt har testats enligt FDA-godkända metoder och har visat sig icke-reaktiva för hepatit B ytantigen (HBsAg), antikroppar mot hepatit C (HCV) och antikroppar mot HIV-1/HIV-2. Denna produkt kan även innehålla annat material av humant ursprung, för vilket godkända tester saknas. Enligt god laboratoriepraxis bör alla material av humant ursprung betraktas som potentiellt infektiösa och hanteras enligt samma försiktighetsregler som patientprover.

Innehåller 5-klor-2-metyl-2H-isotiazol-3-on.

Faroangivelser (H-angivelser) och skyddsangivelser (P-angivelser)

H317 Kan orsaka allergisk hudreaktion. **P261** Undvik att inandas damm / rök / gaser / dimma / ångor / sprej. **P280** Använd skyddshandskar / skyddskläder / ögonskydd / ansiktsskydd. **P272** Nedstänkta arbetskläder får inte avlägsnas från arbetsplatsen. **P363** Nedstänkta kläder ska tvättas innan de används igen. **P333+P313** Vid hudirritation eller utslag: Sök läkarhjälp. **P302+P352** VID HUDKONTAKT: Tvätta med mycket tvål och vatten.

Säkerhetsdatablad (SDS) för laboratoriepersonal finns på *www.bio-rad.com*.

DANSK

Biologisk kildemateriale. Bør behandles som potentiel smittekilde.

Serum fra hver donor, der har leveret urin til fremstilling af dette produkt, er blevet testet med metoder, der er godkendte af FDA, og er fundet ikke-reaktiv over for hepatitis B overfladeantigen (HBsAg), antistof mod hepatitis C (HCV) og antistof mod HIV-1/HIV-2. Dette produkt kan også indeholde andet humant kildemateriale, for hvilket der ikke findes godkendte tests. I overensstemmelse med god laboratoriepraksis bør alle materialer af human oprindelse betragtes som potentiel smittekilde og håndteres efter samme forholdsregler som patientprøver.

Indeholder 5-chlor-2-methyl-2H-isothiazol-3-on.

H-sætninger og P-sætninger

H317 Kan forårsage allergisk hudreaktion. **P261** Undgå indånding af pulver / røg / gas / tåge /damp / spray. **P280** Bær beskyttelseshandsker / beskyttelsestøj / øjenbeskyttelse / ansigtsbeskyttelse. **P272** Tilsmudset arbejdstøj bør ikke fjernes fra arbejdspladsen. **P363** Tilsmudset tøj skal vaskes, før det kan anvendes igen. **P333+P313** Ved hudirritation eller udslet: Søg lægehjælp. **P302+P352** VED KONTAKT MED HUDEN: Vask med rigeligt sæbe og vand.

Professionelle brugere kan få sikkerhedsdatabladet (SDS) på *www.bio-rad.com*.

TÜRKÇE

Biyolojik kaynaklı madde. Potansiyel bulaşıcı olarak muamele edin.

Bu ürün için idrar alınan her bir donörün serumu FDA tarafından kabul edilen yöntemlerle test edilmiştir ve Hepatit B Yüzey Antijeni (HBsAg), Hepatit C'ye karşı antikor (HCV) ve HIV-1/HIV-2'ye karşı antikor açısından reaksiyona yol açmadığı bulunmuştur. Bu ürün aynı zamanda henüz onaylanmış testi bulunmayan diğer insan kaynaklı maddeler de içerebilir. İyi laboratuvar uygulamasına uygun şekilde, tüm insan kaynaklı maddeler potansiyel bulaşıcı olarak dikkate alınmalıdır ve hasta örneklerinde uygulanan önlemlerin aynısı ile kullanılmalıdır.

5-kloro-2-metil-2H-izotiyazol-3-on içerir.

Tehlike (H) ve Önlem (P) Bildirileri

H317 Alerjik cilt reaksiyonuna neden olabilir. **P261** Toz / duman / gaz / buğu / buhar / serpintiyi solumaktan kaçının. **P280** Koruyucu eldiven / koruyucu giysi / göz koruması / yüz koruması kullanın. **P272** Kontamine olmuş iş kıyafetine çalışma alanı dışında izin verilmemelidir. **P363** Tekrar kullanmadan önce kontamine olmuş giysileri yıkayın. **P333+P313** Cilt tahrişi veya döküntü meydana gelirse: Tıbbi tavsiye/bakım alın. **P302+P352** CİLT ÜZERİNE GELDİĞİNDE: Sabun ve su ile iyice yıkayın.

Profesyonel kullanıcılar, Güvenlik Bilgi Formunu (SDS) şu adreste bulabilirler; *www.bio-rad.com*.

日本語

本製品はヒト由来成分を含んでいます。ご使用の際は、感染の可能性があるものとして、検体と同様に十分注意してお取り扱いください。

HBs抗原、HCV抗体、およびHIV-1/2抗体検査は、米国FDA認定試薬を用いて提供者ごとに行い、陰性の結果を得ています。しかし、現在ヒト由来物質を含む製剤の感染性を完全に否定する測定法は確立されておりません。したがって、本製品をご使用の際はGLPに従い、すべてのヒト由来物質に感染の可能性があるものとして、十分注意して取り扱ってください。

5-クロロ-2-メチル-2H-イソチアゾール-3-オンを含有しています。

危険有害性情報（H）および注意書き（P）

H317アレルギー性皮膚反応を起こす恐れがある。**P261**粉じん/煙/ガス/ミスト/蒸気/スプレーの吸入を避ける。**P280**保護手袋/保護衣/保護眼鏡/保護面を着用する。**P272**汚染された作業服を作業場から出さない。**P363**汚染された衣類を再使用する場合には洗濯をする。**P333+P313**皮膚に刺激または発疹が生じた場合、医師の診断/手当てを受ける。**P302+P352**皮膚に付着した場合、多量の水と石鹸で洗う。

安全データシート (SDS) については、diag_jp@bio-rad.com. へお問い合わせください。

GLOSSARY	GLOSSAR	GLOSSAIRE	GLOSSARIO	GLOSARIO	GLOSSÁRIO	ORDLISTA	ORDLISTE
ANALYTES	**ANALYTE**	**ANALYTES**	**ANALITI**	**ANALITOS**	**ANALITOS**	**ANALYTER**	**ANALYTTER**
Bilirubin	Bilirubin	Bilirubine	Bilirubina	Bilirrubina	Bilirrubina	Bilirubin	Bilirubin
Blood	Blut	Sang	Sangue	Sangre	Sangue	Blod	Blod
Casts	Harnzylinder	Cylindres	Cilindri	Cilindros	Cilindros	Cylindrar	Cylindre
Clarity	Klarheit	Clarté	Limpidezza	Claridad	Transparência	Klarhet	Klarhed
Color	Farbe	Couleur	Colore	Color	Cor	Färg	Farve
Creatinine	Creatinin	Créatinine	Creatinina	Creatinina	Creatinina	Kreatinin	Creatinin
Crystals	Kristalle	Cristaux	Cristalli	Cristales	Cristais	Kristaller	Krystaller
Glucose	Glucose	Glucose	Glucosio	Glucosa	Glicose	Glukos	Glucose
hCG (also described as Pregnancy)	hCG (auch als Schwangerschaftshormon bezeichnet)	hCG (également décrit comme Grossesse)	hCG (descritto anche come Gravidanza)	hCG (también descrito como Embarazo)	hCG (também descrito como Gravidez)	hCG (Graviditet)	hCG (graviditet)
Ketones	Keton	Cétones	Chetoni	Cetonas	Cetonas	Ketoner	Ketoner
Leukocytes	Leukozyten	Leucocytes	Leucociti	Leucocitos	Leucócitos	Leukocyter	Leukocytter
Microalbumin	Mikroalbumin	Microalbumine	Microalbumina	Microalbúmina	Microalbumina	Mikroalbumin	Microalbumin
Nitrite	Nitrit	Nitrite	Nitriti	Nitrito	Nitrito	Nitrit	Nitrit
Osmolality	Osmolalität	Osmolalité	Osmolalità	Osmolalidad	Osmolalidade	Osmolalitet	Osmolalitet
pH	pH	pH	pH	pH	pH	pH	pH
Protein, Total	Gesamteiweiß	Protéine, totale	Proteine totali	Proteínas, Totales	Proteína, Total	Protein, totalt	Protein, total
Protein-to-Creatinine Ratio	Protein-Creatinin-Verhältnis	Rapport protéine/créatine	Rapporto proteine-creatinina	Índice proteína/creatinina	Razão proteína/creatinina	Protein-kreatininkvot	Protein-Creatin forhold
Red Blood Cells (RBC)	Erythrozyten (RBC)	Globules rouges (RBC)	Eritrociti (RBC)	Glóbulos rojos (RBC)	Glóbulos vermelhos (RBC)	Erytrocyter (RBC)	Røde blodlegemer (RBC)
Specific Gravity	Spezifisches Gewicht	Gravité spécifique	Peso specifico	Densidad específica	Densidade	Specifik vikt	Vægtfylde
Urobilinogen	Urobilinogen	Urobilinogène	Urobilinogeno	Urobilinógeno	Urobilinogénio	Urobilinogen	Urobilinogen
White Blood Cells (WBC)	Leukozyten (WBC)	Globules blancs (WBC)	Leucociti (WBC)	Leucocitos (WBC)	Glóbulos brancos (WBC)	Leukocyter (WBC)	Hvide blodlegemer (WBC)
TERMS	**BEGRIFFE**	**TERMES**	**TERMINI**	**TÉRMINOS**	**TERMOS**	**TERMER**	**ORDLISTE**
Abnormal	Abnormal	Anormal	Anormale	Anormal	Anormal	Onormal	Abnormal
Absent	Nicht vorhanden	Nul	Assente	Ausente	Ausente	Saknas	Ikke til stede
Amber	Bernsteinfarben	Ambre	Ambra	Ámbar	Âmbar	Bärnsten	Ravgul
Brown	Braun	Brun	Marrone	Marron	Marron	Brun	Bruin
Cells	Zellen	Cellules	Cellule	Células	Células	Celler	Celler
Clear	Klar	Claire	Limpida	Clara	Transparente	Klar	Klar
Cloudy	Wolkig trüb	Trouble	Opaca	Turbia	Turvo	Grumlig	Grumset
Freezing Point Depression	Gefrierpunktserniedrigung	Abaissement du point de congélation	Abbassamento del punto di congelamento	Descenso del punto de congelación	Depressão do ponto de congelação	Fryspunktssänkning	Frysepunktssænkning
Hazy	Schwach trüb	Légèrement trouble	Leggermente opaca	Ligeramente turbia	Ligeiramente Turvo	Svagt grumlig	Let grumset
Large	Groß	Grand	Grande	Grande	Grande	Hög	Stor
Light Yellow	Hellgelb	Jaune clair	Giallo chiaro	Amarilla clara	Amarelo Claro	Ljusgul	Lysegul
Magnification	Vergrößerung	Grossissement	Ingrandimento	Aumento	Ampliação	Förstoring	Forstørrelse
Manufacturer Method	Herstellerverfahren	Méthode du fabricant	Metodo del produttore	Método del fabricante	Método do fabricante	Tillverkningsmetod	Producentens metode
Mean	Mittelwert	Moyenne	Media	Media	Média	Medelvärde	Middelværdi
Moderate	Mäßig	Modéré	Moderato	Moderado	Moderado	Måttlig	Moderat
Negative	Negativ	Négatif	Negativo	Negativo	Negativo	Negativ	Negativ
Normal	Normal	Normal	Normale	Normal	Normal	Normal	Normal
Occasionally present	Gelegentlich Nachweisbar	Présent occasionnellement	Presenza occasionale	Ocasionalmente presente	Ocasionalmente presente	Förekommer ibland	Lejlighedsvis forekommende
Positive	Positiv	Positif	Positivo	Positivo	Positivo	Positiv	Positiv
Present	Vorhanden	Présent	Presente	Presente	Presente	Närvarande	Til stede
Range	Bereich	Plage	Intervallo	Rango	Limites	Område	Område
Red	Rot	Rouge	Rosso	Roja	Vermelho	Röd	Rød
Refractometer	Refraktometer	Réfractomètre	Rifrattometro	Refractómetro	Refractómetro	Refraktometer	Refraktometer
Small	Klein	Petit	Piccolo	Pequeño	Pequeno	Liten	Lille
Straw	Strohgelb	Jaune paille	Paglierina	Color pajizo	Amarelo-Palha	Halmgul	Strågul
Trace	Spur	Trace	Tracce	Trazas	Vestígio	Spårmängd	Sporforekomst
Turbid	Intensiv trüb	Turbide	Torbida	Opaca	Opaco	Kraftigt grumlig	Meget grumset
Units	Einheiten	Unités	Unità di misura	Unidades	Unidades	Enheter	Enheder
Yellow	Gelb	Jaune	Giallo	Amarilla	Amarelo	Gul	Gul

CHEMICAL ANALYSIS

Chemische Analyse // Analyse chimique // Analisi chimica // Análisis químico // Análise química // Kemisk analys // Kemisk analyse

Manufacturer/Method Analyte	Level 1 – 65831	Level 2 – 65832
ACON MISSION / U120 / U500 URINE ANALYZERS		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	25 – 200 Ery/µL (1+ – 3+)
Glucose	Negative	100 – 1000 mg/dL (5 – 60 mmol/L) (± – 3+)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	70 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 300 mg/dL (0.3 – 3.0 g/L) (1+ – 3+)
Specific Gravity	1.005 – 1.025	1.005 – 1.025
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	2 – 8 mg/dL (35 – 140 µmol/L) (1+ – 3+)
ACON MISSION URINALYSIS REAGENT STRIPS (VISUAL) (1)		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	25 – 200 Ery/µL (1+ – 3+)
Glucose	Negative	100 – 1000 mg/dL (5 – 60 mmol/L) (± – 3+)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	70 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 2000 mg/dL (0.3 – 20 g/L) (1+ – 4+)
Specific Gravity	1.005 – 1.025	1.005 – 1.025
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	2 – 12 mg/dL (35 – 200 µmol/L) (1+ – 4+)
ANALYTICON URILYZER / COMBI SCAN URINE ANALYZER		
Bilirubin	Negative	2 – 4 mg/dL (35 – 70 µmol/L) (2+ – 3+)
Blood	Negative	10 – 300 Ery/µL (1+ – 3+)
Glucose	Normal	100 – >1000 mg/dL (5.6 – >56 mmol/L) (2+ – 5+)
Ketones	Negative	10 – 100 mg/dL (1 – 10 mmol/L) ((+) – 2+)
Leukocytes (2)	Negative	Negative – 500 Leu/µL (Negative – 3+)
Nitrite	Negative	Positive
pH	5 – 6	6 – 8
Protein, Total (2)	Negative	Negative / 500 mg/dL (Negative / 5.0 g/L) (Negative / 3+) **(3)**
Specific Gravity	1.010 – 1.025	1.005 – 1.025
Urobilinogen	Normal	8 – 12 mg/dL (140 – 200 µmol/L) (3+ – 4+)
ANALYTICON COMBI SCREEN TEST STRIPS (VISUAL)		
Bilirubin	Negative	2+ – 3+
Blood	Negative	10 – 300 Ery/µL (1+ – 3+)
Glucose	Normal	100 – >1000 mg/dL (5.6 – >56 mmol/L)
Ketones	Negative	Trace / 1+ – 2+
Leukocytes (2)	Negative	Negative – ca. 500 Leu/µL
Nitrite	Negative	Positive
pH	5 – 6	6 – 8
Protein, Total (2)	Negative	Trace / 30 – 500 mg/dL
Specific Gravity	1.005 – 1.020	1.005 – 1.020
Urobilinogen	Normal	8 – 12 mg/dL (140 – 200 µmol/L)
ARKRAY AUTION STICKS 9EB / AUTION MAX AX-4030 / AX-4280 ANALYZERS / AUTION STICKS 9HA / HYBRID AU-4050 ANALYZER		
Bilirubin	Negative	6.0 – ≥10.0 mg/dL (103 – ≥170 µmol/L) (3+ – 4+)
Blood	Negative	0.06 – ≥1.0 mg/dL (0.6 – ≥10.0 mg/L) (1+ – 3+)
Glucose	Normal	150 – ≥1000 mg/dL (8 – ≥56 mmol/L) (2+ – 4+)
Ketones	Negative	10 – 100 mg/dL (1 – 10 mmol/L) (1+ – 3+)
Leukocytes	Negative	75 – 500 Leu/µL
Nitrite	Negative	Positive
pH	5.5 – 6.5	6.5 – 8.5
Protein, Total	Negative	30 – 600 mg/dL (0.3 – 6.0 g/L) (1+ – 3+)
Specific Gravity	1.005 – 1.020	1.015 –1.025
Urobilinogen	Normal	4 – 12 mg/dL (66 – 200 µmol/L) (2+ – 3+)
ARKRAY DIASCREEN 10 REAGENT STRIPS (VISUAL) (1)		
Bilirubin	§	§
Blood	§	§
Glucose	§	§
Ketones	§	§
Leukocytes	§	§
Nitrite	§	§
pH	§	§
Protein, Total	§	§
Specific Gravity	§	§
Urobilinogen	§	§
ARKRAY DIASCREEN 50 URINE CHEMISTRY ANALYZER (1)		
Bilirubin	§	§
Blood	§	§
Glucose	§	§
Ketones	§	§
Leukocytes	§	§
Nitrite	§	§
pH	§	§
Protein, Total	§	§
Specific Gravity	§	§
Urobilinogen	§	§
BECKMAN COULTER ICON 20 hCG		
hCG	Negative	Positive
BTNX RAPID RESPONSE 10 PARAMETERS / RAPID RESPONSE URINE ANALYZER 120 / 500		
Bilirubin	Negative	2 – 4 mg/dL (35 – 70 µmol/L) (2+ – 3+)
Blood	Negative	80 – 200 Ery/µL (2+ – 3+)

Manufacturer/Method Analyte	Level 1 – 65831	Level 2 – 65832
BTNX RAPID RESPONSE 10 PARAMETERS / RAPID RESPONSE URINE ANALYZER 120 / 500 (continued)		
Glucose	Normal	250 – 1000 mg/dL (15 – 60 mmol/L) (1+ – 3+)
Ketones	Negative	5 – 15 mg/dL (0.5 – 1.5 mmol/L) (± – 1+)
Leukocytes	Negative	125 – 500 Leu/µL (2+ – 3+)
Nitrite	Negative	Positive (1+)
pH	5.0 – 6.0	6.0 – 7.0
Protein, Total	Negative	100 – 300 mg/dL (1.0 – 3.0 g/L) (2+ – 3+)
Specific Gravity	1.015 – 1.025	1.010 – 1.020
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	4 – 8 mg/dL (70 – 140 µmol/L) (2+ – 3+)
BTNX RAPID RESPONSE 10 PARAMETER URINALYSIS REAGENT STRIP (VISUAL)		
Bilirubin	Negative	2 – 4 mg/dL (35 – 70 µmol/L) (2+ – 3+)
Blood	Negative	80 – 200 Ery/µL (2+ – 3+)
Glucose	Normal	250 – >2000 mg/dL (15 – >110 mmol/L) (1+ – 4+)
Ketones	Negative	5 – 15 mg/dL (0.5 – 1.5 mmol/L) (± – 1+)
Leukocytes	Negative	70 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive (1+)
pH	5.0 – 6.0	6.0 – 7.0
Protein, Total	Negative	100 – 300 mg/dL (1.0 – 3.0 g/L) (2+ – 3+)
Specific Gravity	1.010 – 1.030	1.010 – 1.020
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	4 – 12 mg/dL (70 – 200 µmol/L) (2+ – 4+)
CLARITY UROCHECK 10SG / UROCHECK 120 URINE ANALYZER		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	25 – 200 Ery/µL (1+ – 3+)
Glucose	Negative	100 – 1000 mg/dL (5 – 60 mmol/L) (± – 3+)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	70 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 300 mg/dL (0.3 – 3.0 g/L) (1+ – 3+)
Specific Gravity	1.005 – 1.025	1.005 – 1.025
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	2 – 8 mg/dL (35 – 140 µmol/L) (1+ – 3+)
CLARITY UROCHECK 10SG URINE REAGENT STRIPS (VISUAL) (1)		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	25 – 200 Ery/µL (1+ – 3+)
Glucose	Negative	100 – 1000 mg/dL (5 – 60 mmol/L) (± – 3+)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	70 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 2000 mg/dL (0.3 – 20 g/L) (1+ – 4+)
Specific Gravity	1.005 – 1.025	1.005 – 1.025
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	2 – 12 mg/dL (35 – 200 µmol/L) (1+ – 4+)
DFI CYBOW SERIES URINE REAGENT STRIPS (VISUAL)		
Bilirubin	Negative	Small – Large (1+ – 3+)
Blood	Negative	10 – 250 RBC/µL (1+ – 3+)
Glucose	Negative	50 – 2000 mg/dL (2.8 – 111 mmol/L)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (Trace – 2+)
Leukocytes	Negative	15 – 500 WBC/µL (Trace – 3+)
Nitrite	Negative	Positive
pH	5 – 6.5	6 – 8
Protein, Total	Negative	15 – 300 mg/dL (0.15– 3.0 g/L) (Trace – 3+)
Specific Gravity	1.005 – 1.020	1.010 – 1.025
Urobilinogen	Normal (0.1 – 1 mg/dL) (1 – 16 µmol/L)	2 – 8 mg/dL (33 – 131 µmol/L)
DFI CYBOW REAGENT STRIPS / DFI CYBOW READER 300		
Bilirubin	Negative	Small – Large (1+ – 3+)
Blood	Negative	10 – 250 RBC/µL (1+ – 3+)
Glucose	Negative	50 – 2000 mg/dL (2.8 – 111 mmol/L)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (Trace – 2+)
Leukocytes	Negative	15 – 500 WBC/µL (Trace – 3+)
Nitrite	Negative	Positive
pH	5 – 6.5	6 – 8
Protein, Total	Negative	15 – 300 mg/dL (0.15– 3.0 g/L) (Trace – 3+)
Specific Gravity	1.005 – 1.020	1.010 – 1.025
Urobilinogen	Normal (0.1 – 1 mg/dL) (1 – 16 µmol/L)	2 – 8 mg/dL (33 – 131 µmol/L)
DFI CYBOW REAGENT STRIPS / DFI CYBOW READER 720		
Bilirubin	Negative	Small – Large (1+ – 3+)
Blood	Negative	10 – 250 RBC/µL (1+ – 3+)
Glucose	Negative	50 – 2000 mg/dL (2.8 – 111 mmol/L)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (Trace – 2+)
Leukocytes	Negative	15 – 500 WBC/µL (Trace – 3+)
Nitrite	Negative	Positive
pH	5 – 6.5	6 – 8
Protein, Total	Negative	15 – 300 mg/dL (0.15– 3.0 g/L) (Trace – 3+)
Specific Gravity	1.005 – 1.020	1.010 – 1.025
Urobilinogen	Normal (0.1 – 1 mg/dL) (1 – 16 µmol/L)	2 – 8 mg/dL (33 – 131 µmol/L)
FISHERBRAND URINE REAGENT STRIPS / AIMSTRIP URINE AUTO ANALYZER / CT-120 URINE ANALYZER		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	25 – 200 Ery/µL (1+ – 3+)
Glucose	Negative	100 – 1000 mg/dL (5 – 60 mmol/L) (± – 3+)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	70 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 300 mg/dL (0.3 – 3.0 g/L) (1+ – 3+)
Specific Gravity	1.005 – 1.025	1.005 – 1.025
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	2 – 8 mg/dL (35 – 140 µmol/L) (1+ – 3+)

Manufacturer/Method Analyte	Level 1 – 65831	Level 2 – 65832
FISHERBRAND URINE REAGENT STRIPS (VISUAL)		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	25 – 200 Ery/µL (1+ – 3+)
Glucose	Negative	100 – 1000 mg/dL (5 – 60 mmol/L) (± – 3+)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	70 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 2000 mg/dL (0.3 – 20 g/L) (1+ – 4+)
Specific Gravity	1.005 – 1.025	1.005 – 1.025
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	2 – 12 mg/dL (35 – 200 µmol/L) (1+ – 4+)
GERMAINE LABORATORIES AIMSTRIP 10-SG URINALYSIS REAGENT STRIP / AIMSTRIP URINE ANALYZER / AIMSTRIP URINE AUTO ANALYZER		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	25 – 200 Ery/µL (1+ – 3+)
Glucose	Negative	100 – 1000 mg/dL (5 – 60 mmol/L) (± – 3+)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	70 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 300 mg/dL (0.3 – 3.0 g/L) (1+ – 3+)
Specific Gravity	1.005 – 1.025	1.005 – 1.025
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	2 – 8 mg/dL (35 – 140 µmol/L) (1+ – 3+)
GERMAINE LABORATORIES AIMSTRIP 10-SG URINALYSIS REAGENT STRIP (VISUAL) (1)		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	25 – 200 Ery/µL (1+ – 3+)
Glucose	Negative	100 – 1000 mg/dL (5 – 60 mmol/L) (± – 3+)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	70 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 2000 mg/dL (0.3 – 20 g/L) (1+ – 4+)
Specific Gravity	1.005 – 1.025	1.005 – 1.025
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	2 – 12 mg/dL (35 – 200 µmol/L) (1+ – 4+)
hCG, OTHER PREGNANCY KIT (4)		
hCG	Negative	Positive
IND URINDSTIX 10LG REAGENT STRIPS		
Bilirubin	Negative	Moderate – Large (2+ – 3+)
Blood	Negative	Moderate – Large (2+ – 3+)
Glucose	Negative	250 – 1000 mg/dL (15 – 60 mmol/L) (1+ – 3+)
Ketones	Negative	15 – 80 mg/dL (1.5 – 8.0 mmol/L) (1+ – 3+)
Leukocytes	Negative	Moderate – Large (2+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 6.5	6.5 – 7.5
Protein, Total	Negative	100 – 300 mg/dL (1.0 – 3.0 g/L) (2+ – 3+)
Specific Gravity	1.010 – 1.020	1.015 – 1.025
Urobilinogen	0.2 – 1.0 EU/dL (3.2 – 16 µmol/L)	4.0 – 8.0 EU/dL (64 – 128 µmol/L)
IRIS DIAGNOSTICS iQ200 SYSTEM / ARKRAY AUTION STICKS 9EB / ARKRAY AUTION MAX AX-4280 ANALYZER		
Bilirubin	Negative	6.0 – ≥10.0 mg/dL (103 – ≥170 µmol/L) (3+ – 4+)
Blood	Negative	0.06 – ≥1.0 mg/dL (0.6 – ≥10.0 mg/L) (1+ – 3+)
Glucose	Normal	150 – ≥1000 mg/dL (8 – ≥56 mmol/L) (2+ – 4+)
Ketones	Negative	10 – 100 mg/dL (1 – 10 mmol/L) (1+ – 3+)
Leukocytes	Negative	75 – 500 Leu/µL
Nitrite	Negative	Positive
pH	5.5 – 6.5	6.5 – 8.5
Protein, Total	Negative	30 – 600 mg/dL (0.3 – 6.0 g/L) (1+ – 3+)
Specific Gravity	1.005 – 1.020	1.015 –1.025
Urobilinogen	Normal	4 – 12 mg/dL (66 – 200 µmol/L) (2+ – 3+)
IRIS DIAGNOSTICS iQ200 SYSTEM - ICHEM VELOCITY STRIPS / AUTOMATED STRIP READER		
Bilirubin	Negative	2 – 4 mg/dL (34 – 70 µmol/L) (1+ – 2+)
Blood	Negative	0.2 – ≥1.0 mg/dL (2.0 – ≥10.0 mg/L) (2+ – 3+)
Glucose	Normal	150 – ≥500 mg/dL (8.3 – ≥28 mmol/L) (2+ – 3+)
Ketones	Negative	5 – 80 mg/dL (0.5 – 8 mmol/L) (Trace – 2+)
Leukocytes	Negative	Negative – 25 Leu/µL (Negative – Trace)
Nitrite	Negative	Negative / Positive
pH	5 – 7	6 – 8
Protein, Total	Negative	30 – ≥500 mg/dL (0.3 – ≥5.0 g/L) (1+ – 3+)
Specific Gravity	1.005 – 1.020	1.011 –1.030
Urobilinogen	Normal	2.0 - 4.0 mg/dL (34 - 70 µmol/L) (1+ - 2+)
JANT PHARMACAL ACCUSTRIP URS 10 (CATALOG NO. UA870) ANALYZER / VISUAL (1)		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	ca. 10 – 250 Ery/µL (1+ – 3+)
Glucose	Negative – Normal	150 – ≥500 mg/dL (8.3 – ≥27.8 mmol/L)
Ketones	Negative	25 – 300 mg/dL (2.5 – 30 mmol/L) (1+ – 3+)
Leukocytes	Negative	ca. 25 – 500 Leuko/µL
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 500 mg/dL (0.3 – 5.0 g/L) (1+ – 3+)
Specific Gravity	1.005 – 1.020	1.005 – 1.025
Urobilinogen	Normal	2 – 12 mg/dL (35 – 200 µmol/L) (1+ – 4+)
JANT PHARMACAL ACCUTEST URS 10 (CATALOG NO. UA710A) ANALYZER / VISUAL (1)		
Bilirubin	Negative	Small – Large (1+ – 3+)
Blood	Negative	Small – Large (25 – 200 Cells/µL) (1+ – 3+)
Glucose	Negative	250 – ≥1000 mg/dL (14 – ≥56 mmol/L) (1+ – ≥3+)
Ketones	Negative	5 – 80 mg/dL (0.5 – 8 mmol/L) (Trace – Large)
Leukocytes	Negative	Small – Large (70 – 500 Cells/µL) (1+ – 3+)
Nitrite	Negative	Positive

Manufacturer/Method Analyte	Level 1 – 65831	Level 2 – 65832
JANT PHARMACAL ACCUTEST URS 10 (CATALOG NO. UA710A) ANALYZER / VISUAL (1) (continued)		
pH	5.0 – 7.0	7.0 – 8.5
Protein, Total	Negative	100 – ≥300 mg/dL (1.0 – ≥3.0 g/L) (2+ – ≥3+)
Specific Gravity	1.005 – 1.015	1.015 – 1.030
Urobilinogen	Normal (0.2 – 1.0 mg/dL) (3.2 – 16 µmol/L)	2.0 – 8.0 mg/dL (32 – 128 µmol/L)
MACHEREY-NAGEL MEDI-TEST COMBI 10 SGL (VISUAL)		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	10 – 250 Ery/µL
Glucose	Negative – Normal	150 – ≥1000 mg/dL (8.3 – ≥55.5 mmol/L)
Ketones	Negative	25 – 300 mg/dL (2.5 – 30 mmol/L) (1+ – 3+)
Leukocytes	Negative	25 – 500 Leu/µL
Nitrite	Negative	Positive
pH	5.0 – 7.0	5.0 – 7.0
Protein, Total	Negative	30 – 500 mg/dL (0.3 – 5.0 g/L)
Specific Gravity	1.005 – 1.020	1.005 – 1.025
Urobilinogen	Normal	4 – 12 mg/dL (70 – 200 µmol/L)
MACHEREY-NAGEL MEDI-TEST COMBI 11 WITH URYXXON 200 ANALYZER		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative – 10 Ery/µL	10 – 250 Ery/µL
Glucose	Negative – Normal	150 – 500 mg/dL (8.3 – 27.8 mmol/L)
Ketones	Negative	25 – 300 mg/dL (2.5 – 30 mmol/L) (1+ – 3+)
Leukocytes	Negative	25 – 500 Leu/µL
Nitrite	Negative	Positive
pH	5.0 – 7.0	5.0 – 7.0
Protein, Total	Negative	30 – 500 mg/dL (0.3 – 5.0 g/L)
Specific Gravity	1.005 – 1.020	1.005 – 1.025
Urobilinogen	Normal	4 – 12 mg/dL (70 – 200 µmol/L)
MACHEREY-NAGEL MEDI-TEST URYXXON STICK 10 WITH URYXXON 300 / 500 / URYXXON RELAX ANALYZERS		
Bilirubin	Negative	1 – 6 mg/dL (17 – 100 µmol/L) (1+ – 3+)
Blood	Negative	10 – 250 Ery/µL
Glucose	Negative – Normal	150 – ≥1000 mg/dL (8.3 – ≥56 mmol/L)
Ketones	Negative	5 – 300 mg/dL (0.5 – 30 mmol/L) (1+ – 3+)
Leukocytes	Negative	15 – 500 Leu/µL
Nitrite	Negative	Positive
pH	5.0 – 7.0	5.0 – 7.0
Protein, Total	Negative	25 – 500 mg/dL (0.25– 5.0 g/L)
Specific Gravity	1.005 – 1.020	1.005 – 1.025
Urobilinogen	Normal	4 – 12 mg/dL (70 – 200 µmol/L)
MCKESSON 10SG URINE REAGENT STRIPS / MCKESSON U120 URINE STRIP ANALYZER		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	25 – 200 Ery/µL (1+ – 3+)
Glucose	Negative	100 – 1000 mg/dL (5 – 60 mmol/L) (± – 3+)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	70 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 300 mg/dL (0.3 – 3.0 g/L) (1+ – 3+)
Specific Gravity	1.005 – 1.025	1.005 – 1.025
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	2 – 8 mg/dL (35 – 140 µmol/L) (1+ – 3+)
MCKESSON 10SG URINE REAGENT STRIPS (VISUAL)		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	25 – 200 Ery/µL (1+ – 3+)
Glucose	Negative	100 – 1000 mg/dL (5 – 60 mmol/L) (± – 3+)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	70 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 2000 mg/dL (0.3 – 20 g/L) (1+ – 4+)
Specific Gravity	1.005 – 1.025	1.005 – 1.025
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	2 – 12 mg/dL (35 – 200 µmol/L) (1+ – 4+)
MEDLINE URINALYSIS STRIPS - 10 PARAMETER URINE REAGENT STRIPS (MPHURN100STR) ANALYZER / VISUAL (1)		
Bilirubin	Negative	Small – Large (1+ – 3+)
Blood	Negative	Small – Large (25 – 200 Cells/µL) (1+ – 3+)
Glucose	Negative	250 – ≥1000 mg/dL (14 – ≥56 mmol/L) (1+ – ≥3+)
Ketones	Negative	5 – 80 mg/dL (0.5 – 8 mmol/L) (Trace – Large)
Leukocytes	Negative	Small – Large (70 – 500 Cells/µL) (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 7.0	7.0 – 8.5
Protein, Total	Negative	100 – ≥300 mg/dL (1.0 – ≥3.0 g/L) (2+ – ≥3+)
Specific Gravity	1.005 – 1.015	1.015 – 1.030
Urobilinogen	Normal (0.2 – 1.0 mg/dL) (3.2 – 16 µmol/L)	2.0 – 8.0 mg/dL (32 – 128 µmol/L)
PROADVANTAGE URINE REAGENT STRIPS 10 PARAMETER / PROADVANTAGE U120 URINE ANALYZER		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	25 – 200 Ery/µL (1+ – 3+)
Glucose	Negative	100 – 1000 mg/dL (5 – 60 mmol/L) (± – 3+)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	70 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 300 mg/dL (0.3 – 3.0 g/L) (1+ – 3+)
Specific Gravity	1.005 – 1.025	1.005 – 1.025
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	2 – 8 mg/dL (35 – 140 µmol/L) (1+ – 3+)
PROADVANTAGE URINE REAGENT STRIPS 10 PARAMETER (VISUAL)		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	25 – 200 Ery/µL (1+ – 3+)
Glucose	Negative	100 – 1000 mg/dL (5 – 60 mmol/L) (± – 3+)

Manufacturer/Method Analyte	Level 1 – 65831	Level 2 – 65832
PROADVANTAGE URINE REAGENT STRIPS 10 PARAMETER (VISUAL) (continued)		
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	70 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 2000 mg/dL (0.3 – 20 g/L) (1+ – 4+)
Specific Gravity	1.005 – 1.025	1.005 – 1.025
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	2 – 12 mg/dL (35 – 200 µmol/L) (1+ – 4+)
QUIDEL QUICKVUE ONE-STEP hCG (1)		
hCG	Negative	Positive
ROCHE CHEMSTRIP 10 URINE TEST STRIPS (VISUAL) (1) (5)		
Bilirubin	Negative	3 – 6 mg/dL (50 – 100 µmol/L) (2+ – 3+)
Blood	Negative	50 – 250 Ery/µL
Glucose	Normal	250 – 1000 mg/dL (14 – 56 mmol/L)
Ketones	Negative	2+ – 3+
Leukocytes	Negative	25 – 500 Leu/µL (Trace – 2+)
Nitrite	Negative	Positive
pH	5 – 7	6 – 8
Protein, Total	Negative	100 – 500 mg/dL (1.0 – 5.0 g/L) (2+ – 3+)
Specific Gravity	1.010 – 1.020	1.005 – 1.015
Urobilinogen	Normal	8 – 12 mg/dL (135 – 203 µmol/L)
ROCHE CHEMSTRIP 101 / URILUX S ANALYZERS (5)		
Bilirubin	Negative	3 – 6 mg/dL (50 – 100 µmol/L) (2+ – 3+)
Blood	Negative	50– 250 Ery/µL (2+ – 3+)
Glucose	Normal	250 – >1000 mg/dL (14 – >56 mmol/L)
Ketones	Negative	15 – 150 mg/dL (1.5 – 15 mmol/L) (1+ – 3+)
Leukocytes	Negative	75 – 500 Leu/µL
Nitrite	Negative	Positive
pH	5 – 7	7 – 8
Protein, Total	Negative	100 – 500 mg/dL (1.0 – 5.0 g/L)
Specific Gravity	1.005 – 1.020	1.000 – 1.015
Urobilinogen	Normal	8 – ≥12 mg/dL (135 – ≥203 µmol/L) (3+ – 4+)
ROCHE CHEMSTRIP CRITERION ANALYZER (5)		
Bilirubin	Negative	3 – 6 mg/dL (50 – 100 µmol/L) (2+ – 3+)
Blood	Negative	150 – 250 Ery/µL (3+ – 4+)
Glucose	Normal	250 – 1000 mg/dL (14 – 56 mmol/L) (2+ – 3+)
Ketones	Negative	50 – 150 mg/dL (5.0 – 15 mmol/L) (2+ – 3+)
Leukocytes	Negative	100 – 500 Leu/µL (2+ – 3+)
Nitrite	Negative	Positive
pH	5 – 6.5	7 – 8
Protein, Total	Negative	100 – 500 mg/dL (1.0 – 5.0 g/L) (2+ – 3+)
Specific Gravity	1.010 – 1.020	1.000 – 1.015
Urobilinogen	Normal	8 – 12 mg/dL (135 – 203 µmol/L) (3+ – 4+)
ROCHE CHEMSTRIP MICRAL (VISUAL) (5)		
Microalbumin	Negative	20 – 100 mg/L
ROCHE CHEMSTRIP MIDITRON JUNIOR ANALYZER (5)		
Bilirubin	Negative	3 – 6 mg/dL (50 – 100 µmol/L) (2+ – 3+)
Blood	Negative	150 – 250 Ery/µL (4+ – 5+)
Glucose	Normal	300 – 1000 mg/dL (18 – 56 mmol/L) (3+ – 4+)
Ketones	Negative	50 – 150 mg/dL (5.0 – 15 mmol/L) (3+ – 4+)
Leukocytes	Negative	100 – 500 Leu/µL (2+ – 3+)
Nitrite	Negative	Positive
pH	5 – 6.5	7 – 8
Protein, Total	Negative	150 – 500 mg/dL (1.5 – 5.0 g/L) (3+ – 4+)
Specific Gravity	1.010 – 1.020	1.000 – 1.015
Urobilinogen	Normal	8 – 12 mg/dL (135 – 203 µmol/L) (3+ – 4+)
ROCHE CHEMSTRIP UA / MIDITRON M ANALYZERS (5)		
Bilirubin	Negative	3 – 6 mg/dL (50 – 100 µmol/L) (2+ – 3+)
Blood	Negative	150 – 250 Ery/µL (3+ – 4+)
Glucose	Normal	100 – 1000 mg/dL (6 – 56 mmol/L) (1+ – 3+)
Ketones	Negative	15 – 150 mg/dL (1.5 – 15 mmol/L) (1+ – 3+)
Leukocytes	Negative	100 – 500 Leu/µL (1+ – 2+)
Nitrite	Negative	Positive
pH	5 – 6.5	7 – 8
Protein, Total	Negative	100 – 500 mg/dL (1.0 – 5.0 g/L) (2+ – 3+)
Specific Gravity	1.010 – 1.020	1.000 – 1.015
Urobilinogen	Normal	8 – 12 mg/dL (135 – 203 µmol/L) (2+ – 3+)
ROCHE URISYS 1100 ANALYZER (5)		
Bilirubin	Negative	3 – 6 mg/dL (50 – 100 µmol/L) (2+ – 3+)
Blood	Negative	50 – 250 Ery/µL (1+ – 2+)
Glucose	Normal	250 – >1000 mg/dL (14 – >56 mmol/L) (2+ – 3+)
Ketones	Negative	50 – 150 mg/dL (5 – 15 mmol/L) (2+ – 3+)
Leukocytes	Negative	75 – 500 Leu/µL (1+ – 2+)
Nitrite	Negative	Positive
pH	5 – 6.5	7 – 8
Protein, Total	Negative	100 – 500 mg/dL (1.0 – 5.0 g/L) (2+ – 3+)
Specific Gravity	1.010 – 1.020	1.000 – 1.020
Urobilinogen	Normal	8 – ≥12 mg/dL (135 – ≥203 µmol/L) (3+ – 4+)
ROCHE URISYS 1800 / COBAS U 411 ANALYZER		
Bilirubin	Negative	3 – 6 mg/dL (50 – 100 µmol/L) (2+ – 3+)
Blood	Negative	150 – 250 Ery/µL (4+ – 5+)
Glucose	Normal	250 – 1000 mg/dL (14 – 56 mmol/L) (3+ – 4+)
Ketones	Negative	50 – 150 mg/dL (5 – 15 mmol/L) (3+ – 4+)
Leukocytes	Negative	25 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive

Manufacturer/Method Analyte	Level 1 – 65831	Level 2 – 65832
ROCHE URISYS 1800 / COBAS U 411 ANALYZER (continued)		
pH	5 – 6.5	7 – 8
Protein, Total	Negative	100 – 500 mg/dL (1.0 – 5.0 g/L) (3+ – 4+)
Specific Gravity	1.010 – 1.020	1.000 – 1.020
Urobilinogen	Normal	8 – 12 mg/dL (135 – 203 µmol/L) (3+ – 4+)
ROCHE URISYS 2400 CASSETTE / URISYS 2400 ANALYZER (1) (5)		
Bilirubin	Negative	3 – 6 mg/dL (50 – 100 µmol/L)
Blood	Negative	150 – 250 Ery/µL
Glucose	Normal	100 – 1000 mg/dL (6 – 56 mmol/L)
Ketones	Negative	50 – 150 mg/dL (5 – 15 mmol/L)
Leukocytes	Negative	100 – 500 Leu/µL
Nitrite	Negative	Positive
pH	5 – 6.5	7 – 8
Protein, Total	Negative	75 – 500 mg/dL (0.75 – 5.00 g/L)
Specific Gravity	1.006 – 1.017	1.016 –1.026
Urobilinogen	Normal	4 – 12 mg/dL (68 – 200 µmol/L)
SEKISUI DIAGNOSTICS / OSOM hCG URINE		
hCG	§	§
SIEMENS ACETEST		
Ketones	Negative	Small – Large
SIEMENS CLINITEK 50		
Bilirubin	Negative	Moderate – Large (2+ – 3+)
Blood	Negative	Moderate – Large (ca. 80 – 200 Ery/µL) (2+ – 3+)
Creatinine	50 – 200 mg/dL (4.4 – 17.7 mmol/L)	100 – 300 mg/dL (8.8 – 26.5 mmol/L)
Glucose	Negative	250 – ≥1000 mg/dL (14 – ≥55 mmol/L) (1+ – 3+)
Ketones	Negative	Trace – ≥80 mg/dL (Trace – ≥7.8 mmol/L) (Trace – 3+)
Leukocytes	Negative	Small – Large (ca. 70 – 500 Leu/µL) (1+ – 3+)
Microalbumin	10 – 30 mg/L	80 – 150 mg/L
Nitrite	Negative	Positive
pH	5.5 – 6.5	6.5 – 8.0
Protein, Total	Negative	100 – ≥300 mg/dL (1.0 – ≥3.0 g/L) (2+ – 3+)
Protein-to-Creatinine Ratio	Normal	Abnormal
Specific Gravity	≤1.005 – 1.015	1.010 – 1.025
Urobilinogen	0.2 – 1.0 EU/dL (3.2 – 16 µmol/L)	4.0 – ≥8.0 EU/dL (66 – ≥131 µmol/L)
SIEMENS CLINITEK 500 / ADVANTUS		
Bilirubin	Negative	Moderate – Large (2+ – 3+)
Blood	Negative	Moderate – Large (ca. 80 – 200 Ery/µL) (2+ – 3+)
Creatinine	50 – 200 mg/dL (4.4 – 17.7 mmol/L)	100 – 300 mg/dL (8.8 – 26.5 mmol/L)
Glucose	Negative	250 – ≥1000 mg/dL (14 – ≥55 mmol/L) (1+ – 3+)
Ketones	Negative	Trace – 40 mg/dL (Trace – 3.9 mmol/L) (Trace – 2+)
Leukocytes	Negative	Small – Large (ca. 70 – 500 Leu/µL) (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.5 – 8.0
Protein, Total	Negative	100 – ≥300 mg/dL (1.0 – ≥3.0 g/L) (2+ – 3+)
Protein-to-Creatinine Ratio	Normal	Abnormal
Specific Gravity	≤1.005 – 1.025	1.010 – ≥1.030
Urobilinogen	0.2 – 1.0 EU/dL (3.2 – 16 µmol/L)	4.0 – ≥8.0 EU/dL (66 – ≥131 µmol/L)
SIEMENS CLINITEK ATLAS		
Bilirubin	Negative	Moderate – Large (2+ – 3+)
Blood	Negative	Moderate – Large (ca. 80 – 200 Ery/µL) (2+ – 3+)
Creatinine	50 – 200 mg/dL (4.4 – 17.7 mmol/L)	100 – ≥300 mg/dL (8.8 – ≥26.5 mmol/L)
Glucose	Negative	250 – ≥1000 mg/dL (14 – ≥55 mmol/L) (1+ – 3+)
Ketones	Negative	40 – ≥160 mg/dL (3.9 – ≥15.6 mmol/L) (2+ – 4+)
Leukocytes	Negative	Small – Large (ca. 70 – 500 Leu/µL) (1+ – 3+)
Nitrite	Negative	Positive
pH	5.5 – 7.0	6.5 – 7.5
Protein, Total	Negative	30 – ≥300 mg/dL (0.3 – ≥3.0 g/L) (1+ – 3+)
Protein-to-Creatinine Ratio	Normal	Abnormal
Specific Gravity	1.005 – 1.015	1.005 – 1.020
Urobilinogen (2)	0.2 – 1.0 EU/dL (3.2 – 16 µmol/L)	1.0 – ≥8.0 EU/dL (16 – ≥131 µmol/L)
SIEMENS CLINITEK MICROALBUMIN (SIEMENS CLINITEK 50 / STATUS)		
Creatinine	50 – 200 mg/dL (4.4 – 17.7 mmol/L)	100 – 300 mg/dL (8.8 – 26.5 mmol/L)
Microalbumin	≤10 – 30 mg/L	80 – ≥150 mg/L
Protein-to-Creatinine Ratio	Normal	Abnormal
SIEMENS CLINITEK STATUS (SOFTWARE VERSION 1.9 OR EARLIER)		
Bilirubin	Negative	Moderate – Large (2+ – 3+)
Blood	Negative	Moderate – Large (ca. 80 – 200 Ery/µL) (2+ – 3+)
Creatinine	50 – 200 mg/dL (4.4 – 17.7 mmol/L)	100 – 300 mg/dL (8.8 – 26.5 mmol/L)
Glucose	Negative	250 – ≥1000 mg/dL (14 – ≥55 mmol/L) (1+ – 3+)
hCG	Negative	Positive
Ketones	Negative	15 – ≥160 mg/dL (1.5 – ≥15.6 mmol/L) (1+ – 4+)
Leukocytes	Negative	Small – Large (ca. 70 – 500 Leu/µL) (1+ – 3+)
Microalbumin	10 – 30 mg/L	80 – 150 mg/L
Nitrite	Negative	Positive
pH	5.5 – 7.0	6.5 – 7.5
Protein, Total	Negative	100 – 300 mg/dL (1.0 – 3.0 g/L) (2+ – 3+)
Protein-to-Creatinine Ratio	Normal	Abnormal
Specific Gravity	1.010 – 1.020	1.015 – 1.025
Urobilinogen	0.2 – 1.0 EU/dL (3.2 – 16 µmol/L)	4.0 – ≥8.0 EU/dL (66 – ≥131 µmol/L)
SIEMENS CLINITEST (5-DROP METHOD)		
Glucose	Negative	1/4% – 2% (0.25 – 2.0 g/dL)
SIEMENS ICTOTEST		
Bilirubin	Negative	Positive

Manufacturer/Method Analyte	Level 1 – 65831	Level 2 – 65832
SIEMENS MULTISTIX 10 SG / PRO (VISUAL) (1)		
Bilirubin	Negative	Moderate – Large (2+ – 3+)
Blood	Negative	Moderate – Large (ca. 80 – 200 Ery/µL) (2+ – 3+)
Creatinine	50 – 200 mg/dL (4.4 – 17.7 mmol/L)	100 – 300 mg/dL (8.8 – 26.5 mmol/L)
Glucose	Negative	250 – 2000 mg/dL (14 – 111 mmol/L) (1+ – 4+)
Ketones	Negative	5 – 80 mg/dL (0.5 – 7.8 mmol/L) (Trace – Large)
Leukocytes	Negative	Small – Large (1+ – 3+)
Nitrite	Negative	Positive
pH	6.0 – 7.0	7.0 – 8.0
Protein, Total	Negative	100 – 2000 mg/dL (1.0 – 20.0 g/L) (2+ – 4+)
Protein-to-Creatinine Ratio	Normal	Abnormal
Specific Gravity	1.005 – 1.015	1.010 – 1.020
Urobilinogen	0.2 – 1.0 EU/dL (3.2 – 16 µmol/L)	4.0 – 8.0 EU/dL (66 – 131 µmol/L)
STANBIO LABORATORY URI-CHEK 10SG URINALYSIS REAGENT STRIPS / URI-TRAK 120 URINE ANALYZER		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	25 – 200 Ery/µL (1+ – 3+)
Glucose	Negative	100 – 1000 mg/dL (5 – 60 mmol/L) (± – 3+)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	70 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 300 mg/dL (0.3 – 3.0 g/L) (1+ – 3+)
Specific Gravity	1.005 – 1.025	1.005 – 1.025
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	2 – 8 mg/dL (35 – 140 µmol/L) (1+ – 3+)
STANBIO LABORATORY URI-CHEK 10SG URINALYSIS REAGENT STRIPS (VISUAL) (1)		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	25 – 200 Ery/µL (1+ – 3+)
Glucose	Negative	100 – 1000 mg/dL (5 – 60 mmol/L) (± – 3+)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	70 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 2000 mg/dL (0.3 – 20 g/L) (1+ – 4+)
Specific Gravity	1.005 – 1.025	1.005 – 1.025
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	2 – 12 mg/dL (35 – 200 µmol/L) (1+ – 4+)
SULFOSALICYLIC ACID (3%)		
Protein, Total (2)	Negative	2+ – 4+
TECO DIAGNOSTICS URS-10 STRIP / URITEK TC-101 ANALYZER		
Bilirubin	Negative	Moderate – Large (2+ – 3+)
Blood	Negative	Moderate – Large (ca. 80 – 200 Ery/µL) (2+ – 3+)
Glucose	Negative	250 – ≥1000 mg/dL (15 – ≥60 mmol/L) (1+ – 3+)
Ketones	Negative	5 – ≥80 mg/dL (0.5 – 8.0 mmol/L) (Trace – Large)
Leukocytes	Negative	Small – Large (ca. 70 – 500 Leu/µL) (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 6.0	6.0 – 8.0
Protein, Total	Negative	30 – ≥300 mg/dL (0.3 – ≥3.0 g/L) (1+ – 3+)
Specific Gravity	≤1.005 – 1.020	1.010 – 1.020
Urobilinogen	0.2 – 1.0 EU/dL (3.2 – 16 µmol/L)	2.0 – ≥8.0 EU/dL (32 – ≥128 µmol/L)
TECO DIAGNOSTICS URS-10 STRIP / URITEK TC-720+ ANALYZER		
Bilirubin	Negative	Moderate – Large (2+ – 3+)
Blood	Negative	Moderate – Large (ca. 80 – 200 Ery/µL) (2+ – 3+)
Glucose	Negative	250 – ≥1000 mg/dL (15 – ≥60 mmol/L) (1+ – 3+)
Ketones	Negative	5 – ≥80 mg/dL (0.5 – 8.0 mmol/L) (Trace – Large)
Leukocytes	Negative	Small – Large (ca. 70 – 500 Leu/µL) (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 6.5	6.0 – 8.0
Protein, Total	Negative	30 – 300 mg/dL (0.3 – 3.0 g/L) (1+ – 3+)
Specific Gravity	1.010 – 1.020	1.015 – ≥1.030
Urobilinogen	0.2 – 1.0 EU/dL (3.2 – 16 µmol/L)	4.0 – ≥8.0 EU/dL (64 – ≥128 µmol/L)
TECO DIAGNOSTICS URS-10 (VISUAL) (1)		
Bilirubin	Negative	Moderate – Large (2+ – 3+)
Blood	Negative	Moderate – Large (ca. 80 – 200 Ery/µL) (2+ – 3+)
Glucose	Negative	250 – 1000 mg/dL (15 – 60 mmol/L) (1+ – 3+)
Ketones	Negative	5 – 80 mg/dL (0.5 – 8.0 mmol/L) (Trace – Large)
Leukocytes	Negative	Small – Large (ca. 70 – 500 Leu/µL) (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 6.5	6.0 – 8.0
Protein, Total (2)	Negative	100 – >2000 mg/dL (1.0 – >20 g/L) (2+ – 4+)
Specific Gravity	1.005 – 1.020	1.010 – 1.030
Urobilinogen	0.2 – 1.0 EU/dL (3.2 – 16 µmol/L)	2.0 – 8.0 EU/dL (32 – 128 µmol/L)
URIT MEDICAL URITEST 10G / 11G REAGENT STRIPS / URITEST-50 / URITEST-500B ANALYZERS		
Bilirubin	Negative	0.5 – 6 mg/dL (8.6 – 100 µmol/L) (1+ – 3+)
Blood	Negative	0.075 – 0.6 mg/dL (25 – 200 Ery/µL) (1+ – 3+)
Glucose	Negative	250 – ≥1000 mg/dL (14 – ≥55 mmol/L) (2+ – 4+)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	15 – 125 Leu/µL (± – 2+)
Nitrite	Negative	Positive
pH	5.5 – 7.0	6.5 – 8.0
Protein, Total	Negative	30 – 300 mg/dL (0.3 – 3.0 g/L) (1+ – 3+)
Specific Gravity	1.010 – 1.020	1.010 – 1.025
Urobilinogen	Normal	2.0 – ≥8.0 EU/dL (33 – ≥131 µmol/L)
YD PREG-Q EARLY PREGNANCY TEST STICK		
hCG	Negative	Positive

Manufacturer/Method Analyte	Level 1 – 65831	Level 2 – 65832
YD URISCAN PRO / PRO+ / OPTIMA / OPTIMA+		
Bilirubin	Negative	1.0 – 3.0 mg/dL (17 – 50 µmol/L) (2+ – 3+)
Blood	Negative	50 – 250 RBC/µL (2+ – 3+)
Glucose	Negative	250 – 2000 mg/dL (14 – 111 mmol/L) (1+ – 4+)
Ketones	Negative	5 – 50 mg/dL (0.5 – 5 mmol/L) (± – 2+)
Leukocytes	Negative	10 – 75 WBC/µL (± – 2+)
Nitrite	Negative	Positive
pH	5.0 – 6.5	6.0 – 7.5
Protein, Total (2)	Negative	10 – 1000 mg/dL (± – 4+)
Specific Gravity	1.010 – 1.025	1.010 – ≥1.030
Urobilinogen	Normal (0.1–1.0 mg/dL) (1.6 – 16 µmol/L)	8 – 12 mg/dL (131 – 197 µmol/L) (3+ – 4+)
YD URISCAN PRO II / OPTIMA II		
Bilirubin	Negative	1.0 – 3.0 mg/dL (17 – 50 µmol/L) (2+ – 3+)
Blood	Negative	50 – 250 RBC/µL (2+ – 3+)
Glucose	Negative	250 – 2000 mg/dL (14 – 111 mmol/L) (1+ – 4+)
Ketones	Negative	5 – 50 mg/dL (0.5 – 5 mmol/L) (± – 2+)
Leukocytes	Negative	10 – 75 WBC/µL (± – 2+)
Nitrite	Negative	Positive
pH	5.0 – 6.5	6.0 – 7.5
Protein, Total (2)	Negative	10 – 1000 mg/dL (± – 4+)
Specific Gravity	≤1.005 – 1.025	1.010 – ≥1.030
Urobilinogen	Normal (0.1–1.0 mg/dL) (1.6 – 16 µmol/L)	8 – 12 mg/dL (131 – 197 µmol/L) (3+ – 4+)
YD URISCAN REAGENT STRIPS (VISUAL)		
Bilirubin	Negative	1.0 – 3.0 mg/dL (17 – 50 µmol/L) (2+ – 3+)
Blood	Negative	50 – 250 RBC/µL (2+ – 3+)
Glucose	Negative	250 – 2000 mg/dL (14 – 111 mmol/L) (1+ – 4+)
Ketones	Negative	5 – 50 mg/dL (0.5 – 5 mmol/L) (± – 2+)
Leukocytes	Negative	10 – 75 WBC/µL (± – 2+)
Nitrite	Negative	Positive
pH	5.0 – 6.5	6.5 – 8.0
Protein, Total	Negative	100 – 1000 mg/dL (2+ – 4+)
Specific Gravity	1.010 – 1.025	1.010 – ≥1.030
Urobilinogen	Normal (0.1–1.0 mg/dL) (1.6 – 16 µmol/L)	8 – 12 mg/dL (131 – 197 µmol/L) (3+ – 4+)
YD URISCAN S-300 ANALYZER		
Bilirubin	Negative	1.0 – 3.0 mg/dL (17 – 50 µmol/L) (2+ – 3+)
Blood	Negative	50 – 250 RBC/µL (2+ – 3+)
Glucose	Negative	100 – 500 mg/dL (5.5 – 28mmol/L) (± – 2+)
Ketones	Negative	Negative **(3)**
Leukocytes	Negative	25 – 500 WBC/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	5.0 – 6.5	6.5 – 8.0
Protein, Total	Negative	100 – 1000 mg/dL (2+ – 4+)
Specific Gravity	1.010 – 1.025	≤1.005 – 1.020
Urobilinogen	Normal (0.1–1.0 mg/dL) (1.6 – 16 µmol/L)	8 – 12 mg/dL (131 – 197 µmol/L) (3+ – 4+)

PHYSICAL PROPERTIES

Physikalische Eigenschaften // Propriétés physiques // Proprietà fisiche // Propiedades físicas // Propriedades físicas // Fysikaliska egenskaper // Fysiske egenskaber

	Units	Level 1 - 65831		Level 2 - 65832		SI	Level 1 - 65831		Level 2 - 65832	
		Mean	Range	Mean	Range		Mean	Range	Mean	Range
Osmolality										
Freezing Point Depression	mOsm/kg	477	382 – 573	767	613 – 920	mmol/kg	477	382 – 573	767	613 – 920
Specific Gravity										
Refractometer		1.013	1.010 – 1.015	1.022	1.018 – 1.027		1.013	1.010 – 1.015	1.022	1.018 – 1.027

OTHER PROPERTIES

Sonstige Eigenschaften // Autres Propriétés // Altre Proprietà // Otras Propiedades // Outras Propriedades // Övriga Egenskaper // Andre Egenskaber

	Level 1 – 65831	Level 2 – 65832
COLOR		
ARKRAY Aution Max AX-4030 / Hybrid AU-4050	Yellow	Yellow
ROCHE cobas u 601	Light Yellow – Yellow	Brown
Siemens Clinitek Atlas	Yellow	Red
Visual	Light Yellow – Yellow	Amber – Brown
CLARITY		
ARKRAY Aution Max AX-4030 / Hybrid AU-4050	Clear - Turbid ((-) – 1+)	Clear - Turbid ((-) – 1+)
ROCHE cobas u 601	Clear - Turbid	Clear - Turbid
Siemens Clinitek Atlas	Clear	Cloudy
Visual	Clear	Clear – Hazy

MICROSCOPIC ANALYSIS (6)

Mikroskopische Analyse // Analyse microscopique // Analisi microscopica // Análisis microscópico // Análise microscópica // Mikroskopisk analys // Mikroskopisk analyse

Manufacturer/Method Analyte	Magnification	Level 1 – 65831	Level 2 – 65832	Units	Level 1 – 65831	Level 2 – 65832
RED BLOOD CELLS (RBC)						
ARKRAY Hybrid AU-4050	Cells/hpf **(7)**	0 – 4	72 – 90	Cells/µL	0 – 20	400 – 500
CenSlide 2000 System	Cells/hpf **(7)**	0 – 5	15 – >100	Cells/hpf **(7)**	0 – 5	15 – >100
IRIS iQ 200 System	Cells/hpf **(7)**	0 – 5	5 – 75	Cells/µL	0 – 28	28 – 417
KOVA System (8)	Cells/hpf **(7)**	0 – 5	10 – >100	Cells/hpf **(7)**	0 – 5	10 – >100
Sediment / Slide & Coverslip	Cells/hpf **(7)**	0 – 5	5 – >100	Cells/hpf **(7)**	0 – 5	5 – >100
Sysmex UF-Series	Cells/hpf **(7)**	0 – 15	65 – 120	Cells/µL	0 – 83	361 – 667
WHITE BLOOD CELLS (WBC)						
ARKRAY Hybrid AU-4050	Cells/hpf **(7)**	0 – 2	9 – 18	Cells/µL	0 – 10	50 – 100
CenSlide 2000 System	Cells/hpf **(7)**	0 – 5	10 – 75	Cells/hpf **(7)**	0 – 5	10 – 75
IRIS iQ 200 System	Cells/hpf **(7)**	0 – 5	15 – 110	Cells/µL	0 – 28	83 – 611
KOVA System (8)	Cells/hpf **(7)**	0 – 5	5 – 60	Cells/hpf **(7)**	0 – 5	5 – 60
Sediment / Slide & Coverslip	Cells/hpf **(7)**	0 – 5	5 – 80	Cells/hpf **(7)**	0 – 5	5 – 80
Sysmex UF-Series	Cells/hpf **(7)**	0 – 5	5 – 25	Cells/µL	0 – 28	28 – 139
CASTS						
ARKRAY Hybrid AU-4050	lpf **(7)**	Absent – Occasionally Present	Absent – Occasionally Present	lpf **(7)**	Absent – Occasionally Present	Absent – Occasionally Present
CenSlide 2000 System	lpf **(7)**	Absent	Absent – Occasionally Present	lpf **(7)**	Absent	Absent – Occasionally Present
IRIS iQ 200 System	lpf **(7)**	Absent	Absent – Occasionally Present	lpf **(7)**	Absent	Absent – Occasionally Present
KOVA System (8)	lpf **(7)**	Absent	Absent – Occasionally Present	lpf **(7)**	Absent	Absent – Occasionally Present
Sediment / Slide & Coverslip	lpf **(7)**	Absent	Absent – Occasionally Present	lpf **(7)**	Absent	Absent – Occasionally Present
Sysmex UF-Series	lpf **(7)**	Absent	Absent – Occasionally Present	lpf **(7)**	Absent	Absent – Occasionally Present
CRYSTALS (9)						
ARKRAY Hybrid AU-4050	lpf **(7)**	Absent	Present **(10)**	lpf **(7)**	Absent	Present **(10)**
CenSlide 2000 System	lpf **(7)**	Absent	Present **(10)**	lpf **(7)**	Absent	Present **(10)**
IRIS iQ 200 System	lpf/hpf **(7)**	Absent	Present **(10)**	lpf/hpf **(7)**	Absent	Present **(10)**
KOVA System (8)	lpf **(7)**	Absent	Present **(10)**	lpf **(7)**	Absent	Present **(10)**
Sediment / Slide & Coverslip	lpf **(7)**	Absent	Present **(10)**	lpf **(7)**	Absent	Present **(10)**
Sysmex UF-Series	lpf **(7)**	Occasionally Present	Present **(10)**	lpf **(7)**	Occasionally Present	Present **(10)**

FOOTNOTES // Fussnoten // Notes de bas de page // Note a pie' pagina // Notas al pie de página // Notas de rodapé // Fotnoter // Fodnoter

ENGLISH

(1) Atypical color may be observed with some analytes. Results based on reaction intensities.
(2) Atypical color observed.
(3) Reaction is positive visually. Instrument reading is negative due to atypical color.
(4) Other test kits with sensitivities of ≥10 mIU/mL.
(5) Roche recommends dipping the strips rather than using dispenser tips.
(6) Bacteria may be present upon microscopic analysis. No claims are made for expected values or stability.
(7) lpf = low power field;
hpf = high power field.
(8) Results were obtained by following the manufacturer's instructions for the KOVA System for Standardized Urinalysis.
(9) Due to the human urine matrix, this product may also contain other common urinary crystals and debris for which no claims are made for expected performance or stability.
(10) This product contains Cystine crystals.
§ The data required to establish the means and acceptable ranges for this assay were not obtained due to limited assignment participation. If your facility is interested in participating in the Value Assignment Program for this assay, please contact your local Bio-Rad Sales or Technical Services Group.
❖ INTERNATIONAL USE ONLY - The following section contains data for methods that are not available for diagnostic use in the United States.

DEUTSCH

(1) Bei einigen Analyten kann eine atypische Farbe beobachtet werden. Ergebnisse basieren auf Reaktionsstärken.
(2) Atypische Färbung beobachtet.
(3) Die Reaktion ist visuell positiv. Der Gerätemesswert ist aufgrund atypischer Färbung negativ.
(4) Andere Testkits mit Empfindlichkeiten von ≥10 mIU/mL.
(5) Roche empfiehlt, die Streifen einzutauchen statt Tropfaufsätze zu verwenden.
(6) Die mikroskopische Analyse zeigt möglicherweise die Anwesenheit von Bakterien. Es können keine Angaben hinsichtlich der erwarteten Werte oder der Stabilität gemacht werden.
(7) lpf = schwache Vergrößerung im Mikroskop (E: low power field); hpf = starke Vergrößerung im Mikroskop (E: high power field).
(8) Die Ergebnisse wurden gemäß der Herstelleranleitung des KOVA System for Standardized Urinalysis ermittelt.
(9) Aufgrund der Humanurinmatrix kann dieses Produkt auch andere normale Harnkristalle und Zelltrümmer enthalten, für deren erwartete Leistungsmerkmale oder Stabilität keine Angaben gemacht werden können.
(10) Dieses Produkt enthält Cystinkristalle.
§ Für die Ermittlung der Zielwerte für diesen Test standen nicht genügend Zielwertermittler zur Verfügung. Falls Ihre Einrichtung interessiert ist, bei künftigen Zielwertermittlungen für diesen Test teilzunehmen, kontaktieren Sie bitte das Kundendienst-Team Ihrer lokalen Bio-Rad Niederlassung.
❖ NUR ZUM GEBRAUCH AUSSERHALB DER USA - Der folgende Abschnitt enthält Zielwertangaben für Tests / Methoden, die in den USA nicht für diagnostische Zwecke erhältlich sind.

FRANÇAIS

(1) Une couleur atypique peut être observée avec certains analytes. Résultats basés sur l'intensité des réactions.
(2) Couleur atypique observée.
(3) Réaction visiblement positive. Le résultat négatif donné par l'appareil est dû à une couleur atypique.
(4) Autres kits de tests avec des sensibilités ≥ à 10 mIU/mL.
(5) Roche recommande de tremper les bandelettes au lieu d'utiliser des bouchons compte-gouttes.
(6) L'analyse microscopique peut révéler la présence de bactéries. Aucune information n'est fournie au sujet des valeurs attendues ou de la stabilité.
(7) cfp= champ de faible puissance;
chp = champ de haute puissance.
(8) Les résultats ont été obtenus en suivant les instructions du fabricant du KOVA System for Standardized Urinalysis.
(9) Étant donné la matrice d'urine humaine, ce produit peut également contenir des cristaux et des débris urinaires pour lesquels aucune revendication n'est faite concernant les performances et la stabilité.
(10) Ce produit contient des cristaux de cystine.
§ Le nombre de données n'a pas été suffisant pour définir la moyenne et les limites acceptables pour ce dosage en raison du manque de laboratoires pour établir ces valeurs. Si votre laboratoire souhaite participer à l'élaboration de ces valeurs, veuillez contacter votre correspondant Bio-Rad.
❖ À UTILISER UNIQUEMENT HORS DES ÉTATS-UNIS - La section suivante contient des données concernant des méthodes qui ne sont pas disponibles pour un usage diagnostique aux États-Unis.

ITALIANO

(1) Con alcuni analiti può essere osservata la comparsa di un colore atipico. Risultati basati sulle intensità di reazione.
(2) Rilevato colore atipico.
(3) La reazione è positiva all'esame visivo. La lettura dello strumento è negativa a causa di una colorazione atipica.
(4) Altri kit di test con sensibilità ≥10 mIU/ml.
(5) Roche raccomanda di immergere le strisce invece di usare dei contagocce.
(6) L'analisi microscopica potrebbe rilevare la presenza di batteri. Non vengono forniti i valori attesi, né i dati di stabilità.
(7) lpf = campi di basso potere;
hpf = campi di alto potere
(8) I risultati sono stati ottenuti seguendo le istruzioni del produttore del KOVA System for Standardized Urinalysis.
(9) A causa della matrice umana dei campioni di urina, questo prodotto potrebbe contenere anche altri cristalli urinari e detriti comuni per i quali non viene fatta alcuna dichiarazione sulle prestazioni o sulla stabilità attese.
(10) Questo prodotto contiene cristalli di cistina.
§ A causa della bassa o nulla partecipazione nell'assegnazione valori, la media e gli intervalli di riferimento per questo dosaggio non sono stati definiti. Contattare gli uffici locali per maggiori chiarimenti.
❖ SOLO PER USO INTERNAZIONALE - La sezione che segue contiene dati per metodi ad uso diagnostico che non sono disponibili negli Stati Uniti.

ESPAÑOL

(1) Puede observarse una coloración atípica en algunos analitos. Resultados basados en intensidades de reacción.
(2) Se observa una coloración atípica.
(3) Reacción positiva a simple vista. Los instrumentos dan una lectura negativa debido a la atipicidad del color.
(4) Otros kits de prueba con sensibilidades de ≥10 mIU/mL.
(5) Roche recomienda mojar las tiras mejor que utilizar tapones goteros.
(6) El análisis microscópico puede revelar la presencia de bacterias. No se garantizan los valores previstos ni la estabilidad.
(7) cpa = campo de poco aumento;
cga = campo de gran aumento;
(8) Resultados obtenidos siguiendo las instrucciones del fabricante para KOVA System for Standardized Urinalysis.
(9) Debido a la matriz de orina humana, el producto puede contener otros cristales y residuos urinarios comunes cuyo comportamiento y estabilidad no están garantizados.
(10) Este producto contiene cristales de cistina.
§ Debido a la baja o nula participación en la asignación de valores, no se ha podido establecer los valores medios y rangos aceptables de este ensayo. Si su centro de trabajo está interesado en participar en la valoración de este ensayo, por favor contacte con su oficina local de Bio-Rad.
❖ SÓLO PARA USO INTERNACIONAL - El siguiente apartado presenta información referente a métodos no disponibles para uso diagnóstico en Estados Unidos.

PORTUGUÊS

(1) Poderá observar-se uma cor atípica com alguns analitos. Resultados com base nas intensidade das reacções.
(2) Cor atípica observada.
(3) A reacção é positiva visualmente. A leitura dos instrumentos é negativa devido à cor atípica.
(4) Outros dispositivos de teste com sensibilidades ≥10 mIU/mL.
(5) A Roche recomenda a introdução das tiras em vez de se utilizar um conta-gotas.
(6) Poderão ser detectadas bactérias após análise microscópica. Não foram feitas quaisquer afirmações em relação aos valores ou estabilidade esperados.
(7) lpf = campo de potência reduzida (low power field);
hpf = campo de potência elevada (high power field);
(8) Os resultados foram obtidos em conformidade com as instruções do fabricante relativas ao sistema KOVA para análises de urina padrão (KOVA System for Standardized Urinalysis).
(9) Devido à matriz da urina humana, este produto também pode conter outros cristais e resíduos urinários comuns para os quais não foram feitas quaisquer afirmações em relação ao desempenho ou estabilidade esperados.
(10) Este produto contém cristais de cistina.
§ Os dados necessários para a obtenção da média e do intervalo de referência para este analíto não foram obtidos dada a limitada participação na atribuição de valores. Se estiver interessado em participar no nosso Programa de Atribuição de Valores, por favor entre em contacto com o seu representante local.
❖ APENAS PARA UTILIZAÇÃO INTERNACIONAL - A secção que se segue contém dados para métodos que não estão disponíveis para utilização em diagnóstico nos Estados Unidos.

SVENSKA

(1) Atypisk färg kan observeras för vissa analyter. Resultaten är baserade på reaktionsintensiteter.
(2) Atypisk färg noterad.
(3) Visuellt positiv reaktion. Negativ instrumentavläsning pga. atypisk färg.
(4) Andra testkit med känslighet på ≥10 mIU/mL.
(5) Roche rekommenderar att man doppar remsorna istället för att använda klämlock.
(6) Bakterier kan eventuellt förekomma vid mikroskopisk analys. Inga utfästelser avseende förväntade värden eller hållbarhetstider görs.
(7) lpf = low power field; fält med låg förstoring
hpf = high power field; fält med hög förstoring
(8) Resultaten erhölls genom att följa tillverkarens anvisningar för KOVA-systemet för standardiserad urinanalys (KOVA System for Standardized Urinalysis).
(9) På grund av den humana urinmatrix kan produkten även innehålla andra vanligt förekommande urinkristaller och partiklar, för vilka inga utfästelser vad gäller förväntad prestanda eller hållbarhet utfärdas.
(10) Denna produkt innehåller cystinkristaller.
§ Nödvändig data för att fastställa medelvärden och acceptabla mätområden för denna analys kunde inte insamlas på grund av ett alltför begränsat deltagarantal vid tilldelning av värden. Om din institution/ditt laboratorium önskar deltaga i programmet för tilldelning av värden (Value Assignment Program) för denna analys, var god kontakta Bio-Rads försäljningsavdelning eller tekniska serviceavdelning.
❖ ENDAST FÖR INTERNATIONELLT BRUK - Följande avsnitt innehåller data för metoder som inte är tillgängliga för diagnostiskt bruk i USA.

DANSK

(1) Unormal farve kan observeres ved visse analytter. Resultaterne er baseret på reaktionsintensitet.
(2) Atypisk farve er konstateret.
(3) Reaktion er positiv visuelt. Instrumentmålingen er negativ pga. atypisk farve.
(4) Andre testkit med følsomhed på ≥10 mIU/ml.
(5) Roche anbefaler, at strimlerne dyppes snarere end at bruge dråbetællerlåg.
(6) Der kan være bakterier til stede ved mikroskopisk analyse. Der er ikke fastsat forventede værdier eller holdbarhed.
(7) lpf = low power field; felt med lav forstørrelse
hpf = high power field; felt med stor forstørrelse
(8) Resultaterne blev indhentet ved at følge producentens anvisninger for KOVA System for standardiseret urinanalyse.
(9) På grund af sammensætningen af human urin kan produktet også indeholde andre hyppigt forekommende urinkrystaller og partikler, for hvilke der ikke er fastsat forventet præstation eller holdbarhed.
(10) Dette produkt indeholder cystinkrystaller.
§ P.g.a. for lille tilslutning til vores "Value Assignment Program" har det desværre ikke været muligt at have middelværdien og standart variationenværdien med på denne analyse. Skulle du/i være iinteresseret i at deltage i dette program for denne analyse, så kontakt venligst det lokale Bio-Rad.
❖ KUN TIL INTERNATIONAL BRUG - Følgende afsnit indeholder data til metoder, der ikke er tilgængelige til diagnostisk anvendelse i USA.

- INTERNATIONAL USE ONLY -

The following section contains data for methods that are not available for diagnostic use in the United States. ❖

INTERNATIONAL USE ONLY -
The following section contains data for methods that are not available for diagnostic use in the United States. ❖

CHEMICAL ANALYSIS
Chemische Analyse // Analyse chimique // Analisi chimica // Análisis químico // Análise química // Kemisk analys // Kemisk analyse

Manufacturer/Method — Analyte	Level 1 – 65831	Level 2 – 65832
77 ELEKTRONIKA LABSTRIP U11PLUS REAGENT STRIP / DOCUREADER / DOCUREADER 2 / HANDUREADER / LABUREADER PLUS / LABUMAT / LABUMAT 2 URINE ANALYZERS / (VISUAL)		
Bilirubin (2)	Negative	1 – 6 mg/dL (17 – 100 µmol/L) (1+ – 3+)
Blood	Negative	ca. 50 – 300 Ery/µL (2+ – 3+)
Glucose	Normal	150 – 1000 mg/dL (8.4 – 56 mmol/L) (2+ – 4+)
Ketones (2)	Negative	15 – 150 mg/dL (1.5 – 15 mmol/L) (1+ – 3+)
Leukocytes (2)	Negative	Negative – 500 Leu/µL (Negative – 3+)
Nitrite	Negative	Positive
pH	5 – 7	6 – 7
Protein, Total (2)	Negative	30 – 500 mg/dL (0.3 – 5 g/L) (1+ – 3+)
Specific Gravity	1.005 – 1.020	1.005 – 1.030
Urobilinogen	Normal	Normal – 12 mg/dL (Normal – 200 µmol/L) (Normal – 4+)
A. MENARINI AUTION MAX AX-4280 / SUPER AUTION SA-4250 ANALYZERS		
Bilirubin	Negative	2 – ≥10 mg/dL (34 – ≥170 µmol/L) (2+ – 4+)
Blood	Negative	0.2 – ≥1 mg/dL (2.0 – ≥10 mg/L) (2+ – 3+)
Glucose	Negative	150 mg/dL – ≥1000 mg/dL (8 – ≥56 mmol/L) (2+ – 4+)
Ketones	Negative	30 – 160mg/dL (3 – 16mmol/L) (2+ – 4+)
Leukocytes	Negative	25 – 500 Leu/µL
Nitrite	Negative	1+ – 2+
pH	6.0 – 7.0	7.0 – 8.0
Protein, Total	Negative	100 – 400 mg/dL (1.0 – 4.0 g/L) (2+ – 3+)
Specific Gravity	1.005 – 1.020	1.011 –1.030
Urobilinogen	0.2 mg/dL (+/-)	2.0 – 12 mg/dL (33 – 200 µmol/L) (1+ – 3+)
ACON MISSION EXPERT / U120 / U500 URINE ANALYZERS		
Bilirubin	Negative	1 – 6 mg/dL (17 – 100 µmol/L) (1+ – 3+)
Blood	Negative	50 – 250 Ery/µL (3+ – 5+)
Creatinine	10 – 100 mg/dL (0.9 – 8.8 mmol/L)	100 – 300 mg/dL (8.8 – 26.5 mmol/L)
Glucose	Negative	100 – 1000 mg/dL (5.5 – 55 mmol/L) (2+ – 4+)
Ketones	Negative	15 – 150 mg/dL (1.5 – 15.0 mmol/L) (2+ – 4+)
Leukocytes	Negative	25 – 500 Leu/µL (1+ – 3+)
Microalbumin	10 – 30 mg/L	80 – 150 mg/L
Nitrite	Negative	Positive
pH	5 – 7	6 – 8
Protein, Total	Negative	75 – 500 mg/dL (0.75 – 5.0 g/L) (2+ – 4+)
Specific Gravity	1.005 – 1.025	1.005 – 1.025
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	4 – 12 mg/dL (70 – 203 µmol/L) (2+ – 4+)
ACON MISSION EXPERT URINALYSIS REAGENT STRIPS (VISUAL) (1)		
Bilirubin	Negative	1 – 6 mg/dL (17 – 100 µmol/L) (1+ – 3+)
Blood	Negative	50 – 250 Ery/µL (3+ – 4+)
Creatinine	10 – 100 mg/dL (0.9 – 8.8 mmol/L)	100 – 300 mg/dL (8.8 – 26.5 mmol/L)
Glucose	Negative	100 – 1000 mg/dL (5.5 – 55 mmol/L) (2+ – 4+)
Ketones	Negative	10 – 150 mg/dL (1.0 – 15.0 mmol/L) (1+ – 3+)
Leukocytes	Negative	25 – 500 Leu/µL (1+ – 3+)
Microalbumin	10 – 30 mg/L	80 – 150 mg/L
Nitrite	Negative	Positive
pH	5 – 7	6 – 8
Protein, Total	Negative	30 – 500 mg/dL (0.3 – 5 g/L) (1+ – 3+)
Specific Gravity	1.005 – 1.025	1.005 – 1.025
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	4 – 12 mg/dL (70 – 200 µmol/L) (2+ – 4+)
ACON MISSION / U500 URINE ANALYZER		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	25 – 200 Ery/µL (1+ – 3+)
Creatinine	10 – 100 mg/dL (0.9 – 8.8 mmol/L)	100 – 300 mg/dL (8.8 – 26.5 mmol/L)
Glucose	Negative	100 – 1000 mg/dL (5 – 60 mmol/L) (± – 3+)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	70 – 500 Leu/µL (1+ – 3+)
Microalbumin	10 – 30 mg/L	80 – 150 mg/L
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 300 mg/dL (0.3 – 3.0 g/L) (1+ – 3+)
Specific Gravity	1.005 – 1.025	1.005 – 1.025
Urobilinogen	0.2 mg/dL (3.5 µmol/L)	2 – 8 mg/dL (35 – 140 µmol/L) (1+ – 3+)
DFI CYBOW / COMBOSTIK / DUS URINE REAGENT STRIPS (VISUAL)		
Bilirubin	Negative	Small – Large (1+ – 3+)
Blood	Negative	10 – 250 RBC/µL (1+ – 3+)
Creatinine	50 – 200 mg/dL (4.4 – 17.7 mmol/L)	100 – 300 mg/dL (8.8 – 26.5 mmol/L)
Glucose	Negative	50 – 2000 mg/dL (2.8 – 111 mmol/L)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (Trace – 2+)
Leukocytes	Negative	15 – 500 WBC/µL (Trace – 3+)
Microalbumin	10 mg/L	150 mg/L
Nitrite	Negative	Positive
pH	5 – 6.5	6 – 8
Protein, Total	Negative	15 – 300 mg/dL (0.15– 3.0 g/L) (Trace – 3+)
Protein-to-Creatinine Ratio	Normal	Abnormal
Specific Gravity	1.005 – 1.020	1.010 – 1.025
Urobilinogen	Normal (0.1 – 1 mg/dL) (1 – 16 µmol/L)	2 – 8 mg/dL (33 – 131 µmol/L)
DFI CYBOW R-50 / COMBOSTIK R-50 / DUS R-50 / CYBOW R-50S / COMBOSTIK R-50S / DUS R-50S		
Bilirubin	Negative	Small – Large (1+ – 3+)
Blood	Negative	10 – 250 RBC/µL (1+ – 3+)

INTERNATIONAL USE ONLY -
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Manufacturer/Method Analyte	Level 1 – 65831	Level 2 – 65832
DFI CYBOW R-50 / COMBOSTIK R-50 / DUS R-50 / CYBOW R-50S / COMBOSTIK R-50S / DUS R-50S (continued)		
Creatinine	50 – 200 mg/dL (4.4 – 17.7 mmol/L)	100 – 300 mg/dL (8.8 – 26.5 mmol/L)
Glucose	Negative	50 – 2000 mg/dL (2.8 – 111 mmol/L)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (Trace – 2+)
Leukocytes	Negative	15 – 500 WBC/µL (Trace – 3+)
Microalbumin	10 mg/L	150 mg/L
Nitrite	Negative	Positive
pH	5 – 6.5	6 – 8
Protein, Total	Negative	15 – 300 mg/dL (0.15– 3.0 g/L) (Trace – 3+)
Protein-to-Creatinine Ratio	Normal	Abnormal
Specific Gravity	1.005 – 1.020	1.010 – 1.025
Urobilinogen	Normal (0.1 – 1 mg/dL) (1 – 16 µmol/L)	2 – 8 mg/dL (33 – 131 µmol/L)
DFI CYBOW READER 300 / COMBOSTIK R-300 / DUS R-300		
Bilirubin	Negative	Small – Large (1+ – 3+)
Blood	Negative	10 – 250 RBC/µL (1+ – 3+)
Creatinine	50 – 200 mg/dL (4.4 – 17.7 mmol/L)	100 – 300 mg/dL (8.8 – 26.5 mmol/L)
Glucose	Negative	50 – 2000 mg/dL (2.8 – 111 mmol/L)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (Trace – 2+)
Leukocytes	Negative	15 – 500 WBC/µL (Trace – 3+)
Microalbumin	10 mg/L	150 mg/L
Nitrite	Negative	Positive
pH	5 – 6.5	6 – 8
Protein, Total	Negative	15 – 300 mg/dL (0.15– 3.0 g/L) (Trace – 3+)
Protein-to-Creatinine Ratio	Normal	Abnormal
Specific Gravity	1.005 – 1.020	1.010 – 1.025
Urobilinogen	Normal (0.1 – 1 mg/dL) (1 – 16 µmol/L)	2 – 8 mg/dL (33 – 131 µmol/L)
DFI CYBOW READER 720 / COMBOSTIK R-700 / DUS R-720		
Bilirubin	Negative	Small – Large (1+ – 3+)
Blood	Negative	10 – 250 RBC/µL (1+ – 3+)
Creatinine	50 – 200 mg/dL (4.4 – 17.7 mmol/L)	100 – 300 mg/dL (8.8 – 26.5 mmol/L)
Glucose	Negative	50 – 2000 mg/dL (2.8 – 111 mmol/L)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (Trace – 2+)
Leukocytes	Negative	15 – 500 WBC/µL (Trace – 3+)
Microalbumin	10 mg/L	150 mg/L
Nitrite	Negative	Positive
pH	5 – 6.5	6 – 8
Protein, Total	Negative	15 – 300 mg/dL (0.15– 3.0 g/L) (Trace – 3+)
Protein-to-Creatinine Ratio	Normal	Abnormal
Specific Gravity	1.005 – 1.020	1.010 – 1.025
Urobilinogen	Normal (0.1 – 1 mg/dL) (1 – 16 µmol/L)	2 – 8 mg/dL (33 – 131 µmol/L)
ERBA LACHEMA DEKAPHAN LAURA STRIPS / LAURA URINE ANALYZER		
Bilirubin	Negative	3 – 6 mg/dL (51 – 103 µmol/L) (2+ – 3+)
Blood	Negative	50 – 250 Ery/µL (2+ – 3+)
Glucose	Negative	300 – 1000 mg/dL (17 – 55 mmol/L) (3+ – 4+)
Ketones	Negative	5.2 – 52 mg/dL (0.5 – 5 mmol/L) (± – 2+)
Leukocytes	Negative	75 – 500 Leu/µL (2+ – 3+)
Nitrite	Negative	Positive
pH	5 – 6.5	7 – 8
Protein, Total	Negative	30 – 500 mg/dL (0.3 – 5 g/L) (1+ – 3+)
Specific Gravity	1.010 – 1.020	1.005 – 1.015
Urobilinogen (2)	Normal	6 – 12 mg/dL (102 – 203 µmol/L) (3+ – 4+)
ERBA LACHEMA DEKAPHAN LAURA STRIPS / LAURA M URINE ANALYZER		
Bilirubin	Negative	3 – 6 mg/dL (51 – 103 µmol/L) (2+ – 3+)
Blood	Negative	50 – 250 Ery/µL (2+ – 3+)
Glucose	Negative	300 – 1000 mg/dL (17 – 55 mmol/L) (3+ – 4+)
Ketones	Negative	16 – 52 mg/dL (1.5 – 5 mmol/L) (1+ – 2+)
Leukocytes	Negative	25 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	≤6 – 7	≤6 – 8
Protein, Total	Negative	30 – 500 mg/dL (0.3 – 5 g/L) (1+ – 3+)
Specific Gravity	1.015 – 1.025	1.010 – 1.025
Urobilinogen (2)	Normal	1 – 12 mg/dL (17 – 203 µmol/L) (1+ – 4+)
ERBA LACHEMA DEKAPHAN LAURA STRIPS / LAURA SMART URINE ANALYZER		
Bilirubin	Negative	3 – 6 mg/dL (51 – 103 µmol/L) (2+ – 3+)
Blood	Negative	50 – 250 Ery/µL (2+ – 3+)
Glucose	Negative	300 – 1000 mg/dL (17 – 55 mmol/L) (3+ – 4+)
Ketones	Negative	5.2 – 52 mg/dL (0.5 – 5 mmol/L) (± – 2+)
Leukocytes	Negative	75 – 500 Leu/µL (2+ – 3+)
Nitrite	Negative	Positive
pH	5 – 6.5	7 – 8
Protein, Total	Negative	30 – 500 mg/dL (0.3 – 5 g/L) (1+ – 3+)
Specific Gravity	1.010 – 1.020	1.005 – 1.015
Urobilinogen (2)	Normal	3 – 12 mg/dL (51 – 203 µmol/L) (2+ – 4+)
ERBA LACHEMA DEKAPHAN LAURA STRIPS (VISUAL)		
Bilirubin	Negative	3 – 6 mg/dL (51 – 103 µmol/L) (2+ – 3+)
Blood	Negative	50 – 250 Ery/µL (2+ – 3+)
Glucose	Negative	300 – 1000 mg/dL (17 – 55 mmol/L) (3+ – 4+)
Ketones	Negative	16 – 52 mg/dL (1.5 – 5 mmol/L) (1+ – 2+)
Leukocytes	Negative	75 – 500 Leu/µL (2+ – 3+)
Nitrite	Negative	Positive
pH	5 – 6	7 – 8

INTERNATIONAL USE ONLY -
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Manufacturer/Method Analyte	Level 1 – 65831	Level 2 – 65832
ERBA LACHEMA DEKAPHAN LAURA STRIPS (VISUAL) (continued)		
Protein, Total	Negative	100 – 500 mg/dL (1 – 5 g/L) (2+ – 3+)
Specific Gravity	1.015 – 1.025	1.005 – 1.015
Urobilinogen (2)	Normal	6 – 12 mg/dL (102 – 203 µmol/L) (3+ – 4+)
ERBA MANNHEIM URO-DIP 10E STRIPS / LAURA M URINE ANALYZER		
Bilirubin	Negative	3 – 6 mg/dL (51 – 103 µmol/L) (2+ – 3+)
Blood	Negative	50 – 250 Ery/µL (2+ – 3+)
Glucose	Negative	300 – 1000 mg/dL (17 – 55 mmol/L) (3+ – 4+)
Ketones	Negative	16 – 52 mg/dL (1.5 – 5 mmol/L) (1+ – 2+)
Leukocytes	Negative	25 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	≤6 – 7	≤6 – 8
Protein, Total	Negative	30 – 500 mg/dL (0.3 – 5 g/L) (1+ – 3+)
Specific Gravity	1.015 – 1.025	1.010 – 1.025
Urobilinogen (2)	Normal	1 – 12 mg/dL (17 – 203 µmol/L) (1+ – 4+)
ERBA MANNHEIM URO-DIP 10E STRIPS / URO-DIPCHECK 240E URINE ANALYZER		
Bilirubin	Negative	3 – 6 mg/dL (51 – 103 µmol/L) (2+ – 3+)
Blood	Negative	50 – 250 Ery/µL (2+ – 3+)
Glucose	Negative	300 – 1000 mg/dL (17 – 55 mmol/L) (3+ – 4+)
Ketones	Negative	5.2 – 52 mg/dL (0.5 – 5 mmol/L) (± – 2+)
Leukocytes	Negative	75 – 500 Leu/µL (2+ – 3+)
Nitrite	Negative	Positive
pH	5 – 6.5	7 – 8
Protein, Total	Negative	30 – 500 mg/dL (0.3 – 5 g/L) (1+ – 3+)
Specific Gravity	1.010 – 1.020	1.005 – 1.015
Urobilinogen (2)	Normal	3 – 12 mg/dL (51 – 203 µmol/L) (2+ – 4+)
ERBA MANNHEIM URO-DIP 10E STRIPS / URO-DIPCHECK 400E URINE ANALYZER		
Bilirubin	Negative	3 – 6 mg/dL (51 – 103 µmol/L) (2+ – 3+)
Blood	Negative	50 – 250 Ery/µL (2+ – 3+)
Glucose	Negative	300 – 1000 mg/dL (17 – 55 mmol/L) (3+ – 4+)
Ketones	Negative	5.2 – 52 mg/dL (0.5 – 5 mmol/L) (± – 2+)
Leukocytes	Negative	75 – 500 Leu/µL (2+ – 3+)
Nitrite	Negative	Positive
pH	5 – 6.5	7 – 8
Protein, Total	Negative	30 – 500 mg/dL (0.3 – 5 g/L) (1+ – 3+)
Specific Gravity	1.010 – 1.020	1.005 – 1.015
Urobilinogen (2)	Normal	6 – 12 mg/dL (102 – 203 µmol/L) (3+ – 4+)
ERBA MANNHEIM URO-DIP 10E STRIPS (VISUAL)		
Bilirubin	Negative	3 – 6 mg/dL (51 – 103 µmol/L) (2+ – 3+)
Blood	Negative	50 – 250 Ery/µL (2+ – 3+)
Glucose	Negative	300 – 1000 mg/dL (17 – 55 mmol/L) (3+ – 4+)
Ketones	Negative	16 – 52 mg/dL (1.5 – 5 mmol/L) (1+ – 2+)
Leukocytes	Negative	75 – 500 Leu/µL (2+ – 3+)
Nitrite	Negative	Positive
pH	5 – 6	7 – 8
Protein, Total	Negative	100 – 500 mg/dL (1 – 5 g/L) (2+ – 3+)
Specific Gravity	1.015 – 1.025	1.005 – 1.015
Urobilinogen (2)	Normal	6 – 12 mg/dL (102 – 203 µmol/L) (3+ – 4+)
FORTRESS DIAGNOSTICS URINE STRIPS 10 PARAMETER - URS00010 (VISUAL)		
Bilirubin	Negative	2+ – 3+
Blood	Negative	50 – 250 Ery/µl
Glucose	Negative	150 – ≥1000 mg/dL (8 – ≥60 mmol/L)
Ketones	Negative	1+ – 3+
Leukocytes	Negative	25 – 500 Leu/µL
Nitrite	Negative	Positive
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 500 mg/dL (0.3 – 5.0 g/L)
Specific Gravity	1.005 – 1.015	1.000 – 1.010
Urobilinogen	Normal	8 – 12 mg/dL (140 – 200 µmol/L)
FORTRESS DIAGNOSTICS URINE STRIP PROTEIN / GLUCOSE - URS002GP (VISUAL)		
Glucose	Negative	150 – ≥1000 mg/dL (8 – ≥60 mmol/L)
Protein, Total	Negative	30 – 500 mg/dL (0.3 – 5.0 g/L)
FORTRESS DIAGNOSTICS URINE STRIP PROTEIN / KETONES / GLUCOSE - URS03GPK (VISUAL)		
Glucose	Negative	150 – ≥1000 mg/dL (8 – ≥60 mmol/L)
Ketones	Negative	1+ – 3+
Protein, Total	Negative	30 – 500 mg/dL (0.3 – 5.0 g/L)
FORTRESS DIAGNOSTICS URINE STRIP PROTEIN / GLUCOSE / PH - URS03GPP (VISUAL)		
Glucose	Negative	150 – ≥1000 mg/dL (8 – ≥60 mmol/L)
pH	5.0 – 7.0	6.0 – 8.0
Protein, Total	Negative	30 – 500 mg/dL (0.3 – 5.0 g/L)
FORTRESS DIAGNOSTICS hCG SERUM / URINE STRIP - HCGSU050 (VISUAL)		
hCG	Negative	Positive
FORTRESS DIAGNOSTICS hCG URINE STRIP - HCGS100 (VISUAL)		
hCG	Negative	Positive
FORTRESS DIAGNOSTICS hCG SERUM / URINE DEVICE - HCGSU040 (VISUAL)		
hCG	Negative	Positive

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Manufacturer/Method Analyte	Level 1 – 65831	Level 2 – 65832
FORTRESS DIAGNOSTICS hCG URINE DEVICE - HCGC0040 (VISUAL)		
hCG	Negative	Positive
HITADO hCG STRIP TEST (PRODUCT ID: 35285602 / 35285603 / 35285613 / 35285623		
hCG	Negative	Positive
HITADO HCG CASSETTE TEST (PRODUCT ID: 35300601 / 35300602 / 35300603		
hCG	Negative	Positive
HITADO NOBISTRIP U10 (PRODUCT ID: 38810601) (VISUAL)		
Bilirubin	Negative	1 – 4 mg/dL (17 – 70 µmol/L) (1+ – 3+)
Blood	Negative	<50 Ery/µL
Glucose	Normal	100 – ≥2000 mg/dL (5 – ≥110 mmol/L) (± – 4+)
Ketones	Negative	5 – 160 mg/dL (0.5 – 16 mmol/L) (± – 4+)
Leukocytes	Negative	15 – 500 Leu/µL (± – 3+)
Nitrite	Negative	Positive
pH	5 – 7	5 – 9
Protein, Total	Negative	15 – 2000 mg/dL (0.15 – 20 g/L) (± – 4+)
Specific Gravity	1.005 – 1.015	1.000 – 1.030
Urobilinogen	Normal	1 – 12 mg/dL (17 – 200 µmol/L)
HUMAN COMBINA 10M TEST STRIP (VISUAL)		
Bilirubin	Negative	2+ – 3+
Blood	Negative	ca. 50 – 250 Ery/µL
Glucose	Negative	300 – 1000 mg/dL (17 – 55 mmol/L)
Ketones	Negative	16 – 52 mg/dL (1.5 – 5 mmol/L)
Leukocytes	Negative	75 – 500 Leu/µL
Nitrite	Negative	Positive
pH	5 – 7	5 – 7
Protein, Total	Negative	100 – 500 mg/dL (1 – 5 g/L)
Specific Gravity	1.010 – 1.020	1.005 – 1.015
Urobilinogen	Normal	6 – 12 mg/dL (102 – 203 µmol/L)
HUMAN COMBINA 11S TEST STRIP (VISUAL) / COMBILYZER PLUS / COMBILYZER VA ANALYZERS		
Bilirubin	Negative	2 – 4 mg/dL 35 – 100 µmol/L (2+ – 3+)
Blood	Negative	ca. 50 – 300 Ery/µL
Glucose	Normal	500 – 1000 mg/dL (28 – 56 mmol/L)
Ketones	Negative	1.5 – 15 mmol/L (1+ – 3+)
Leukocytes	Negative	Negative – 75 Leu/µL
Nitrite	Negative	Positive
pH	5 – 6	6 – 8
Protein, Total (2)	Negative	100 – 500 mg/dL (1 – 5 g/L)
Specific Gravity	1.005 – 1.020	1.005 – 1.020
Urobilinogen	Normal	8 – 12 mg/dL (140 – 200 µmol/L)
HUMAN COMBINA 13 TEST STRIP (VISUAL) / HUMAN COMBILYZER 13 ANALYZER		
Bilirubin	Negative	51 – 103 µmol/L (2+ – 3+)
Blood	Negative	ca. 80 – 200 Ery/µL (2+ – 3+)
Creatinine	10 – 100 mg/dL (0.9 – 8.8 mmol/L)	200 – 300 mg/dL (17.7 – 26.5 mmol/L)
Glucose	Normal	250 – 1000 mg/dL (14 – 56 mmol/L)
Ketones	Negative	15 – 78 mg/dL (1.5 – 7.8 mmol/L)
Leukocytes	Negative	70 – 500 Leu/µL
Microalbumin	10 mg/L	80 – 150 mg/L
Nitrite	Negative	Positive
pH	5.0 – 6.5	6.0 – 7.0
Protein, Total	Negative	300 – 2000 mg/dL (3.0 – 20 g/L)
Protein-to-Creatinine Ratio	Normal (<3.4 mg/mmol)	Abnormal (3.4 – 33.9 mg/mmol)
Specific Gravity	1.010– 1.020	1.015 – 1.025
Urobilinogen	(0.2 mg/dL) (3.4 µmol/L)	4 – 8 mg/dL (68 – 135 µmol/L)
ROCHE COBAS U 411 ANALYZER (INTERNATIONAL CONCENTRATIONS SETTING) (5)		
Bilirubin	Negative	3 – 6 mg/dL (50 – 100 µmol/L) (2+ – 3+)
Blood	Negative	150 – 250 Ery/µL (4+ – 5+)
Glucose	Normal	300 – 1000 mg/dL (14 – 56 mmol/L) (3+ – 4+)
Ketones	Negative	50 – 150 mg/dL (5 – 15 mmol/L) (3+ – 4+)
Leukocytes	Negative	25 – 500 Leu/µL (1+ – 3+)
Nitrite	Negative	Positive
pH	5 – 6.5	7 – 8
Protein, Total	Negative	75 – 500 mg/dL (0.75 – 5.00 g/L) (2+ – 4+)
Specific Gravity	1.010 – 1.020	1.000 – 1.020
Urobilinogen	Normal	8 – 12 mg/dL (135 – 203 µmol/L) (3+ – 4+)
ROCHE COBAS U PACK CASSETTE / COBAS U 601 ANALYZER (5)		
Bilirubin	Negative	3 – 6 mg/dL (50 – 100 µmol/L) (2+ – 3+)
Blood	Negative	150 – 250 Ery/µL (4+ – 5+)
Glucose	Normal	300 – 1000 mg/dL (17 – 56 mmol/L) (3+ – 4+)
Ketones	Negative	50 – 150 mg/dL (5 – 15 mmol/L) (3+ – 4+)
Leukocytes	Negative	100 – 500 Leu/µL (2+ – 3+)
Nitrite	Negative	Positive
pH	5 – 6.5	7 – 8
Protein, Total	Negative	150 – 500 mg/dL (1.5 – 5.0 g/L) (3+ – 4+)
Specific Gravity	1.007 – 1.018	1.016 – 1.028
Urobilinogen	Normal	8 – 12 mg/dL (140 – 203 µmol/L) (3+ – 4+)
ROCHE COMBUR-TEST URINE TEST STRIPS (VISUAL) (1) (5)		
Bilirubin	Negative	3 – 6 mg/dL (50 – 100 µmol/L) (2+ – 3+)
Blood	Negative	50 – 250 Ery/µL
Glucose	Normal	250 – 1000 mg/dL (14 – 56 mmol/L)

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Manufacturer/Method Analyte	Level 1 – 65831	Level 2 – 65832
ROCHE COMBUR-TEST URINE TEST STRIPS (VISUAL) (1) (5) (continued)		
Ketones	Negative	50 – 150 mg/dL (5.0 – 15 mmol/L) (2+ – 3+)
Leukocytes	Negative	25 – 500 Leu/µL (Trace – 2+)
Nitrite	Negative	Positive
pH	5 – 7	6 – 8
Protein, Total	Negative	100 – 500 mg/dL (1.0 – 5.0 g/L) (2+ – 3+)
Specific Gravity	1.010 – 1.020	1.005 – 1.015
Urobilinogen	Normal	8 – 12 mg/dL (135 – 203 µmol/L) (3+ – 4+)
ROCHE URISYS 1100 ANALYZER (INTERNATIONAL CONCENTRATIONS SETTING) (5)		
Bilirubin	Negative	3 – 6 mg/dL (50 – 100 µmol/L) (2+ – 3+)
Blood	Negative	50 – 250 Ery/µL (3+ – 4+)
Glucose	Normal	300 – 1000 mg/dL (17 – 56 mmol/L) (3+ – 4+)
Ketones	Negative	50 – 150 mg/dL (5 – 15 mmol/L) (2+ – 3+)
Leukocytes	Negative	100 – 500 Leu/µL (2+ – 3+)
Nitrite	Negative	Positive
pH	5 – 6.5	7 – 8
Protein, Total	Negative	150 – 500 mg/dL (1.5 – 5.0 g/L) (3+ – 4+)
Specific Gravity	1.010 – 1.020	1.000 – 1.020
Urobilinogen	Normal	8 – 12 mg/dL (140 – 200 µmol/L) (3+ – 4+)
SD UROCOLOR 10 REAGENT STRIPS (VISUAL) (1)		
Bilirubin (2)	Negative	0.5 – 3.0 mg/dL (8 – 50 µmol/µL) (1+ – 3+)
Blood	Negative	10 – 250 RBC/µL (1+ – 3+)
Glucose	Negative	250 – 2000 mg/dL (14 – 112 mmol/L) (1+ – 4+)
Ketones (2)	Negative	5 – 50 mg/dL (0.5 – 5.0 mmol/L) (Trace – 2+)
Leukocytes (2)	Negative	25 – 75 WBC/µL (1+ – 2+)
Nitrite	Negative	Positive
pH	5.5 – 6.5	6.5 – 7.5
Protein, Total	Negative	10 – 100 mg/dL (0.1 – 1.0 g/L) (Trace – 2+)
Specific Gravity	1.015 – 1.025	1.010 – 1.020
Urobilinogen	Negative	4 – 12 mg/dL (68 – 204 µmol/L) (2+ – 4+)
SD UROCOLOR 10 REAGENT STRIPS / UROMETER 120 / UROMETER 720 ANALYZERS (1)		
Bilirubin (2)	Negative	0.5 – 3.0 mg/dL (8 – 50 µmol/µL) (1+ – 3+)
Blood	Negative	10 – 250 RBC/µL (1+ – 3+)
Glucose	Negative	250 – 2000 mg/dL (14 – 112 mmol/L) (1+ – 4+)
Ketones (2)	Negative	5 – 50 mg/dL (0.5 – 5.0 mmol/L) (Trace – 2+)
Leukocytes (2)	Negative	25 – 75 WBC/µL (1+ – 2+)
Nitrite	Negative	Positive
pH	5.5 - 6.5	6.5 – 7.5
Protein, Total	Negative	10 – 100 mg/dL (0.1 – 1.0 g/L) (Trace – 2+)
Specific Gravity	1.015 - 1.025	1.010 – 1.020
Urobilinogen	Negative	4.0 – 12 mg/dL (68 – 204 µmol/L) (2+ – 4+)
URIT MEDICAL URITEST 10G / 11G REAGENT STRIPS / URIT-500C ANALYZER		
Bilirubin	Negative	0.5 – 6 mg/dL (8.6 – 100 µmol/L) (1+ – 3+)
Blood	Negative	0.075 – 0.6 mg/dL (25 – 200 Cell/µL) (1+ – 3+)
Glucose	Negative	250 – ≥1000 mg/dL (14 – ≥55 mmol/L) (2+ – 4+)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	15 – 125 Cell/µL (± – 2+)
Nitrite	Negative	Positive
pH	5.5 – 7.0	6.5 – 8.0
Protein, Total	Negative	30 – 300 mg/dL (0.3 – 3.0 g/L) (1+ – 3+)
Specific Gravity	1.010 – 1.020	1.010 – 1.025
Urobilinogen	Normal	2.0 – ≥8.0 EU/dL (33 – ≥131 µmol/L)
URIT MEDICAL URIT 11F REAGENT STRIP / URIT-1500 ANALYZER		
Bilirubin	Negative	0.5 – 6 mg/dL (8.6 – 100 µmol/L) (1+ – 3+)
Blood	Negative	0.075 – 0.6 mg/dL (25 – 200 Ery/µL) (1+ – 3+)
Glucose	Negative	250 – ≥1000 mg/dL (14 – ≥55 mmol/L) (2+ – 4+)
Ketones	Negative	5 – 40 mg/dL (0.5 – 4.0 mmol/L) (± – 2+)
Leukocytes	Negative	15 – 125 Leu/µL (± – 2+)
Nitrite	Negative	Positive
pH	5.5 – 7.0	6.5 – 8.0
Protein, Total	Negative	30 – 300 mg/dL (0.3 – 3.0 g/L) (1+ – 3+)
Specific Gravity	1.005 – 1.020	1.010 – 1.025
Urobilinogen	Normal	2.0 – ≥8.0 EU/dL (33 – ≥131 µmol/L)
YD URISCAN SUPER		
Bilirubin	Negative	1.0 – 3.0 mg/dL (17 – 50 µmol/L) (2+ – 3+)
Blood	Negative	50 – 250 RBC/µL (2+ – 3+)
Glucose	Negative	250 – 2000 mg/dL (14 – 111 mmol/L) (1+ – 4+)
Ketones	Negative	5 – 50 mg/dL (0.5 – 5 mmol/L) (± – 2+)
Leukocytes	Negative	10 – 75 WBC/µL (± – 2+)
Nitrite	Negative	Positive
pH	5.0 – 6.5	6.0 – 7.5
Protein, Total (2)	Negative	10 – 1000 mg/dL (± – 4+)
Specific Gravity	1.006 – 1.020	1.013 – 1.030
Urobilinogen	Normal (0.1–1.0 mg/dL) (1.6 – 16 µmol/L)	8 – 12 mg/dL (131 – 197 µmol/L) (3+ – 4+)

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MICROSCOPIC ANALYSIS (6)
Mikroskopische Analyse // Analyse microscopique // Analisi microscopica // Análisis microscópico // Análise microscópica // Mikroskopisk analys // Mikroskopisk analyse

Manufacturer/Method	Analyte	Magnification	Level 1 – 65831	Level 2 – 65832	Units	Level 1 – 65831	Level 2 – 65832
RED BLOOD CELLS (RBC)							
77 Elektronika UriSed / sediMAX / COBIO XS		Cells/hpf **(7)**	0 – 1	30 – 90	Cells/µL	0 – 2	140 – 400
Roche cobas u 701		Cells/hpf **(7)**	0 – 6	72 – 216	Cells/µL	0 – 25	315 – 960
WHITE BLOOD CELLS (WBC)							
77 Elektronika UriSed / sediMAX / COBIO XS		Cells/hpf **(7)**	0 – 1	5 – 20	Cells/µL	0 – 2	24 – 81
Roche cobas u 701		Cells/hpf **(7)**	0 – 6	13 – 39	Cells/µL	0 – 25	55 – 175
CASTS							
77 Elektronika UriSed / sediMAX / COBIO XS		lpf **(7)**	Absent	Absent	lpf **(7)**	Absent	Absent
CRYSTALS (9)							
77 Elektronika UriSed / sediMAX / COBIO XS		lpf **(7)**	Occasionally Present	Present **(10)**	lpf **(7)**	Occasionally Present	Present **(10)**
Roche cobas u 701		lpf **(7)**	Absent	Present **(10)**	lpf **(7)**	Absent	Present **(10)**

MANUFACTURERS LISTED // Angegebene Hersteller // Fabricants indiqués // Produttori elencati // Lista de fabricante // Fabricantes enunciados // Angivna tillverkare // Anførte producenter

77 Electronika Kft., Budapest, Hungary
A. Menarini, Firenze, Italy
ACON Laboratories Inc., San Diego, California
Analyticon Biotechnologies AG, Lichtenfels, Germany
Arkray, Kyoto, Japan
Beckman Coulter Inc., Fullerton, California
BTNX Inc., Markham, Ontario, Canada
DFI Co., Ltd., Gyung-Nam, Republic of Korea
Diagnostic Test Group (Clarity), Boca Raton, Florida
Erba Lachema s.r.o., Brno, Czech Republic
Fortress Diagnostics Ltd., Antrim, Northern Ireland, United Kingdom
Germaine Laboratories, Inc., San Antonio, Texas
Hitado Diagnostics GmbH, Möhnesee-Delecke, Germany
Human Gesellschaft für Biochemika und Diagnostika mbH, Wiesbaden, Germany
HYCOR Biomedical, Garden Grove, California
Iris Diagnostics, Chatsworth, California
Jant Pharmacal Corp., Encino, California
Macherey-Nagel GmbH & Co. KG, Dueren, Germany
McKesson, San Francisco, California
Medline Industries, Inc., Mundelein, Illinois
NDC Inc., Nashville, Tennessee
Quidel Corp., San Diego, California
Roche Diagnostics Corporation, Indianapolis, Indiana
Roche Diagnostics GmbH, Mannheim, Germany
Sekisui Diagnostics LLC, Farmington, Massachusetts
Siemens Healthcare Diagnostics Inc., Tarrytown, New York
Stanbio Laboratory, Boerne, Texas
Standard Diagnostics, Inc., Kyonggi-do, Korea
StatSpin Inc., Norwood, Massachusetts
Sysmex America Inc., Mundelein, Illinois
Teco Diagnostics, Anaheim, California
Thermo Fisher Scientific, Waltham, Massachusetts
URIT Medical Electronic Co. Ltd., Guangxi, China
YD Diagnostics, Kyunggi-Do, Korea

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5258A

Urinalysis Control

2

An assayed human urinalysis control.
Kontrolle (human) für Urinanalysen, mit Zielwertangaben.
Contrôle titré d'analyse des urines humaines.
Controllo dosato per l'analisi delle urine umane.
Control humano valorado para urianálisis.
Controlo humano ensaiado de análise de urina.
En analyserad human urinanalyskontroll.
En analyseret human urinanalysekontrol.

Level 2
12 x 12 mL

IVD

2°C 8°C

LOT 65832

EXP 2016-11-30

(01)00847661000556(17)161130(10)65832

UNITED STATES, *Bio-Rad Laboratories*
9500 Jeronimo Road, Irvine, CA 92618

EC REP **FRANCE,** *Bio-Rad*
3 boulevard Raymond Poincaré, 92430 Marnes-la-Coquette

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436

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5258A

Urinalysis Control

1

An assayed human urinalysis control.
Kontrolle (human) für Urinanalysen, mit Zielwertangaben.
Contrôle titré d'analyse des urines humaines.
Controllo dosato per l'analisi delle urine umane.
Control humano valorado para urianálisis.
Controlo humano ensaiado de análise de urina.
En analyserad human urinanalyskontroll.
En analyseret human urinanalysekontrol.

Level 1
12 x 12 mL

IVD

2°C 8°C

LOT 65831

EXP 2016-11-30

(01)00847661000549(17)161130(10)65831

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435X

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Urinalysis Control

Bilevel
MiniPak

An assayed human urinalysis control.
Kontrolle (human) für Urinanalysen, mit Zielwertangaben.
Contrôle titré d'analyse des urines humaines.
Controllo dosato per l'analisi delle urine umane.
Control humano valorado para urianálisis.
Controlo humano ensaiado de análise de urina.
En analyserad human urinanalyskontroll.
En analyseret human urinanalysekontrol.

2 x 12 mL
(1 per level)

IVD

2°C 8°C

LOT 65830

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5258B

Urinalysis Control

Bilevel

An assayed human urinalysis control.
Kontrolle (human) für Urinanalysen, mit Zielwertangaben.
Contrôle titré d'analyse des urines humaines.
Controllo dosato per l'analisi delle urine umane.
Control humano valorado para urianálisis.
Controlo humano ensaiado de análise de urina.
En analyserad human urinanalyskontroll.
En analyseret human urinanalysekontrol.

12 x 12 mL
(6 per level)

IVD

2°C 8°C

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